

Management of Financial Conflict of Interest in PHS-Funded Projects

A. INTRODUCTION

ATGC Inc. (“ATGC”, or “Company”) is dedicated to the development of novel research tools and therapeutic products. ATGC’s financial conflict of interest (FCOI) policy meets the expectation that the design, conduct, and reporting of research will be free from bias resulting from financial interests, and that potential financial conflicts of interests are properly identified, managed, reduced, or eliminated. This policy provides a framework to comply with requirements of 42 CFR 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research” set forth by the Public Health Service (PHS), which includes the National Institutes of Health (NIH) for its sponsored research projects.

B. DEFINITIONS

The following definitions are used in this document.

- **Senior/Key Personnel:** The Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the ATGC in the grant application, progress report, or any other report submitted to the PHS/NIH by ATGC under the regulation.
- **Investigator:** The project director or principal investigator (PD/PI) 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 subgrantees, contractors, consortium participants, collaborators or consultants.
- **Institution:** Any domestic or foreign entity or organization that submits a proposal to, or receives research funding from PHS. ATGC is considered an “Institution” for the purposes of this policy.
- **Institutional responsibilities:** Any key/senior personnel/investigator’s professional responsibilities conducted on behalf of ATGC and as defined by ATGC, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards (IRB) or Data and Safety Monitoring Boards (DSMB).
- **Financial Interest:** Anything of non-trivial monetary value, regardless of whether the value is readily ascertainable.
- **Remuneration:** Salary and any payment for services, including consulting fees, honoraria, and paid authorship.
- **Financial Conflict of Interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.
- **Significant Financial Interest (SFI):** Financial interest consisting of one or more of the following interests of the investigator/senior/key personnel (and those of the investigator/senior/key personnel’s spouse and dependent children) that reasonably appears to be related to the Investigator/senior/key personnel’s institutional responsibilities:
 - i. 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 the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and 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 remunerations from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator/senior/key personnel (or the Investigator/senior/key personnel 's spouse or dependent children) holds any equity interests (e.g., stock, stock options, 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.
 - iv. 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 excluded sources provided in regulation.
- **SFI Exclusions:** the SFI does not include the following types of financial interests: salaries, royalties or other remuneration paid by ATGC Therapeutics, Inc. to the investigator/senior/key personnel if the investigator/senior/key personnel is currently employed or otherwise appointed by ATGC, including intellectual property rights assigned to ATGC and agreements to share in royalties related to such rights; any ownership interest in ATGC held by the investigator/senior/key personnel; income from investment vehicles, such as mutual funds and retirements accounts, as long as the investigator/senior/key 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, 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.
 - **Designated FCOI Official(s):** Person(s) responsible for the implementation of the FCOI Policy, designated by ATGC. On Jan 1, 2022, the Company's Chief Executive Officer (CEO) is designated as the FCOI Official. The term is three years.

C. SCOPE

This policy is applicable to each employee who is planning to or is participating in research activity that is either partially or wholly supported by PHS funds. Each such employee must:

- i. **Disclose** his or her significant financial interests (SFI) in non-ATGC entities that would appear to be related to the employee's professional responsibilities on behalf of ATGC;
- ii. **Comply** with a FCOI management plan, if a FCOI is identified; and
- iii. **Undergo** FCOI training, once every year.

Disclosure of SFI is essential for ATGC to determine if a FCOI exists, and in cases of FCOI determine how it will be managed and reported in full compliance with government regulation. Non-disclosure of SFI or non-compliance with FCOI management plan may subject the employee to employment discipline including, without limitation, suspension or termination of employment.

D. POLICY

Employees who are planning to or participating in research activity that is either partially or wholly supported by PHS funds must receive FCOI training (refer to Section E6.), disclose their SFI to the designated FCOI Official.

The Company FCOI will follow the Protocol for Handling Financial Conflict of Interest (refer to Section E). The FCOI Official will determine whether the SFI constitutes an FCOI. If the SFI is determined to be an FCOI, the Company FCOI Official will review and development an FCOI management plan consistent with government regulation and, furthermore, to promptly notify the PHS funding component (e.g., NIH) via a FCOI report.

If a bias is found, ATGC shall submit a mitigation report to the NIH, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias.

ATGC will work with the investigator/senior/key personnel to set up an FCOI management plan to mitigate the situation. As a part of the FCOI management plan, the Company FCOI Official may decide one or more actions depending upon the situation, including requiring certain disclosure in public presentations, employee role reassignment, reduction or elimination of the financial interest sanctions (e.g., sale of an equity interest) or severance of relationships that create financial conflicts.

Any FCOI should be managed, reduced, or eliminated within sixty (60) days of its identification by the Company FCOI Official.

Companywide, the senior/key personnel/investigator is required to disclose the FCOI in each public presentation with research results.

This policy shall also apply when, in the course of an ongoing PHS-funded research project, an investigator and/or senior/key personnel who is new to participating in the research project discloses a significant financial interest or an existing investigator and or senior/key personnel discloses a new significant financial interest to ATGC.

If an investigator and/or senior/key personnel fails to comply with the Company FCOI policy, within 120 days of the implementation of the FCOI management plan, ATGC shall complete a retrospective review of the senior/key personnel/investigator's activities to determine the appropriate plan to mitigate this bias. In extreme cases, the investigator and/or the senior/key personnel may lose the right to work on the project.

E. IMPLEMENTATION

The designated Company FCOI Official is responsible for implementation of the FCOI policy. A step-by-step guideline is outlined below.

Protocol for Handling Financial Conflict of Interest

This document specifies the FCOI protocol for PHS-funded research: that is the step-by-step implementation of the ATGC FCOI policy.

E1. Who is required to disclose financial interests

Employees planning to or participating in research activity that is either partially or wholly supported by PHS funds are required to disclose financial interests (“PHS-funded Investigators”).

E2. How to disclose SFI

PHS-funded Investigators are required to disclose SFIs to the ATGC FCOI Official, as follows:

- i. Employees planning to participate in PHS-funded research are required to disclose all SFIs prior to submission of an application for PHS-funded research.
- ii. Once the research project has been funded all PHS-funded investigators shall submit SFI Disclosures within thirty (30) days of acquiring any new or increased SFI.
- iii. When a new investigator joins an ongoing PHS-funded project, the investigator shall submit SFI disclosures within thirty (30) days of joining the project.
- iv. All PHS-funded investigators shall submit an updated SFI disclosure annually.
- v. SFI disclosures (except travel) must include the following information:
 - a. Identity of the sponsor/organizer; and
 - b. Nature of SFI (e.g., salary, license income, stock).
- vi. Externally funded travel also constitutes SFI. PHS-funded investigators shall submit SFI Disclosures for externally funded travel: prior to submission of an application for PHS-funded research; and for PHS-funded projects within thirty (30) days of externally funded travel and in an annual update. The following travel related information must be disclosed:
 - a. Purpose
 - b. Identity of the sponsor/organizer,
 - c. Destination, and,
 - d. Duration.

E3. Review of disclosures

All SFI disclosures will be reviewed by the designated FCOI Official. The review will determine whether an SFI is related to the PHS-funded research and therefore an FCOI. The designated FCOI Official may involve the relevant investigator in the review, and request additional information from the investigator.

E4. Management of FCOI

For each disclosure that leads to determination of FCOI, the FCOI Official will develop a management plan. PHS-funded Investigators with an identified FCOI must comply with the management plan. The management plan will include the following elements at a minimum:

- i. The role and principal duties of the conflicted PHS-funded Investigator in the research project;
- ii. Conditions of the management plan (see examples below);
- iii. How the management plan is designed to safeguard objectivity in the research project;
- iv. Confirmation of the PHS-funded Investigator's agreement to the management plan; and
- v. How the management plan will be monitored to ensure PHS-funded Investigator compliance.

Examples of conditions or restrictions that might be imposed to manage a PHS-funded Investigator's FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board(s));
- For research projects involving human subjects research, 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 FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

E5. Reporting FCOI to PHS Awarding Component (e.g., the NIH)

Based on the FCOI management plan, the designated FCOI Official will submit an initial FCOI report to the PHS-funding component, for example NIH. The report will be submitted, for example using eRA Commons for NIH, and consist of all elements required by the regulation.

The FCOI report will be submitted prior to the expenditure of funds under the Notice of Award. FCOIs identified during the period of award will be submitted to NIH within sixty (60) days of identification, including for new investigators joining an ongoing PHS-funded project.

Annual FCOI reports will also be submitted and will include the status of financial conflict, i.e., whether the financial conflict is still being managed or explains why the financial conflict no longer exists. These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

E6. Training for FCOI

PHS-funded Investigators must undergo training with respect to this Policy and PHS FCOI rules and regulations, as follows:

1. When a new employee joins the Company;
2. Prior to participating in PHS-funded research, and once every year;
3. When the Company FCOI policy changes in a manner that effects PHS-funded Investigator disclosure or compliance requirements; and,
4. If Company FCOI Official determines that a PHS-funded Investigator is not compliant with the FCOI Policy or an FCOI Management Plan.

NIH web-based training (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) will be used. Employees must save and print the FCOI Certificate as proof of completion.

E7. Noncompliance and remedies

If an investigator has failed to comply with a management plan or, for whatever reason, an FCOI is one that was not identified, reviewed or managed in a timely manner, the designated Company FCOI Official shall, within 120 days of the determination of noncompliance, conduct a retrospective review of the investigator's activities and the research project to determine whether any PHS-funded research or portion thereof conducted during the period of noncompliance was biased in design, conduct or reporting. The review shall be documented consistent with the FCOI Regulations [§60.605(a)(3)(ii)(B)]. If bias is found during the course of the review, the designated Company FCOI Official will promptly notify the PHS Awarding Component (which may take its own action and/or require further action by ATGC and/or the investigator, as it deems appropriate) and submit a mitigation report consistent with the FCOI Regulations [§60.605(a)(3)(iii)]. If appropriate, the designated Company FCOI Official will update the previously submitted FCOI report. In any event, the designated Company FCOI Official shall submit FCOI reports annually thereafter.

E8. Retention of records

Records of financial disclosures and any resulting action will be maintained for three (3) years from the date of submission of the final expenditures report.

E9. Subrecipient compliance

When working with a subrecipient, a written agreement will be put in place to clarify: (a) which organization's (prime awardee or subrecipient) FCOI policy will be followed, and, (b) in either case, clarify the timeline for disclosure and reporting. Note that the prime awardee is responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest.

E10. Public Accessibility

ATGC's Financial Conflict of Interest Policy shall be posted on the public portion of the ATGC website. In addition, upon receipt of a written request for information concerning identified FCOI's

held by Senior/Key Personnel (as defined by regulation), ATGC will make that information available within five (5) business days of the request. The information shall include all elements required by 42 CFR Part 50, updated through the date of the response.

F. RESOURCES

- NIH's "FCOI Training" on the regulation on its FCOI webpage for at <https://grants.nih.gov/grants/policy/coi/index.htm>.
- Section 4.1.10 Financial Conflict of Interest at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm
- Section 15.2.1 Consortium Agreements, Written Agreement at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15.2_administrative_and_other_requirements.htm
- 45 CFR Part 94 (contracts) <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
- NIH's FAQ E.20. related to a \$5,000 threshold for IP rights and interests at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=question53050>.