



ASGCT FINANCIAL CONFLICT OF INTEREST POLICY FOR U.S. PUBLIC HEALTH SERVICE-SUPPORTED PROGRAMS

Additional information on 42 CFR Part 50, Subpart F (Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought) is available through the [NIH website](#).

PURPOSE

This American Society for Gene and Cell Therapy (ASGCT) Financial Conflict of Interest (FCOI) Policy provides guidance for Principal Investigators (PIs), directors, faculty, staff, and other planners involved in the design, conduct, or reporting of ASGCT projects seeking or receiving PHS-funded grants, subawards, or cooperative agreements. This policy only applies to projects that are applying for or have received PHS-funded grants, subawards, or cooperative agreements.

This policy is intended to meet the requirements stated in I 42 CFR Part 50, Subpart F, for promoting objectivity in research and ensuring that the design, conduct and reporting of PHS-funded research is free from bias that may arise from an individual's perceived or real FCOI and applies to all individuals who submit PHS applications or receive PHS-funded grants, subawards, or cooperative agreements administered by the ASGCT.

DISCLOSURE PROCEDURES

Principal Investigators (PIs), directors, faculty, staff, and other planners who are involved in the design, conduct, or reporting of PHS applications or PHS-funded grants, subawards, or cooperative agreements must:

1. Disclose financial interests (see SUBMISSION OF DISCLOSURES) at the time of the PHS application by completing the ASGCT Financial Conflict of Interest PHS Disclosure Form
2. Submit an ASGCT Financial Conflict of Interest PHS Disclosure Form on an annual basis for each PHS-funded grant, subaward, or cooperative agreement administered by the ASGCT
3. Provide notice to the ASGCT within 30 (thirty) days of any changes (acquisition, purchase, inheritance, etc.) to their ASGCT Financial Conflict of Interest PHS Disclosure Form
4. Complete Financial Conflict of Interest training at least once every four (4) years; when associated with a PHS application; when deemed not in compliance by the ASGCT; or as otherwise required by the ASGCT to remain in compliance with 42 CFR Part 50, Subpart F.



Individuals must confirm that they have [completed the NIH tutorial](#) by submitting a copy of the Certificate of Completion to the ASGCT

SUBMISSION OF DISCLOSURES

Principal Investigators (PIs), directors, faculty, staff, and other planners who are involved in the design, conduct, or reporting of PHS-funded grants, subawards, or cooperative agreements must disclose to the ASGCT any financial interest consisting of one or more of the following interests (including those of the Investigator's spouse and dependent children) that reasonably appears to be related to the responsibilities related to PHS applications or PHS-funded grants, subawards, or cooperative agreements:

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

Principal Investigators (PIs), directors, faculty, staff, and other planners must also disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on their behalf and not reimbursed so that the exact monetary value may not be readily available), related to PHS-funded grants, subawards, or cooperative agreements responsibilities (applications or funded projects); 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.



Principal Investigators (PIs), directors, faculty, staff, and other planners must 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. ASGCT may request additional information pertaining to these disclosures to determine whether the travel constitutes a potential violation of 42 CFR 50, Subpart F. The ASGCT requires that Principal Investigators (PIs), directors, faculty, staff, and other planners provide the information requested on disclosure forms for ASGCT projects seeking or receiving PHS-funded grants, subawards, or cooperative agreements. Those who fail to provide the information will not be permitted to participate in these ASGCT projects.

DISCLOSURE REVIEW

ASGCT will review all disclosures for compliance with 42 CFR 50, Subpart F, and the guidelines above. If a FCOI is identified by the ASGCT that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research or application, the ASGCT may request additional information for the disclosure to manage the FCOI. FCOIs may be approved with certain restrictions or conditions or may be prohibited at the discretion of the ASGCT. Management plans to resolve may be developed and monitored by the ASGCT and will be completed prior to the expenditure of any funds under a PHS grant, subaward, or cooperative agreement.

ASGCT will complete the review of any individual who is new to a PHS-funded research project or application, and any previously associated individuals who disclose new and/or additional information within 60 (sixty) days of receipt of the disclosure.

COMPLIANCE REPORTING TO THE PHS

Prior to the expenditure of any funds under a PHS-funded project, the ASGCT will provide the funder with an FCOI report regarding any individual's significant financial interest determined to be conflicting and confirm that a management plan has been developed and implemented. ASGCT will provide notice to the funder of any new individuals or existing individuals who have changes to the disclosure following the initial FCOI report during an active PHS-funded project within 60 (sixty) days.

FCOI reports will include (at a minimum) the following:

1. Project number
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used

3. Name of the individual with the financial conflict of interest
4. Name of the entity with which the individual has a financial conflict of interest
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
6. Monetary value of the financial interest (in U.S. dollars) 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
7. Description of how the financial interest relates to the PHS-funded research and the basis for the ASGCT's determination that the financial interest conflicts with such research
8. Description of the key elements of the ASGCT management plan, including:
 - a. Role and principal duties of the conflicted individual in the PHS-funded project or application
 - b. Conditions of the management plan
 - c. How the management plan is designed to safeguard objectivity in the research project
 - d. Confirmation of the individual's agreement to the management plan
 - e. How the management plan will be monitored to ensure compliance
 - f. Other information as needed

ASGCT will provide the funder with an annual FCOI report that addresses the status of any financial conflicts of interest and any changes to the management plan(s) for the duration of the PHS-funded research. This report will note whether the financial conflict(s) is still being managed or explain why the financial conflict(s) has been resolved. FCOI reports will be provided for the duration of the PHS-funded project according to the submission procedures provided by the funder.

NON-COMPLIANCE REPORTING

Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the individual to disclose a significant financial interest that is determined by the ASGCT to constitute a financial conflict of interest; failure by the ASGCT to review or manage such a financial conflict of interest; or failure by the individual to comply with a financial conflict of interest management plan, the ASGCT will, within 120 days of the ASGCT's determination of noncompliance, complete a retrospective review of the individual's activities and the PHS-funded



research project to determine whether any PHS-funded project, or portion thereof, conducted during the period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The ASGCT is required to document the review and include the following:

1. Project number
2. Project title
3. PD/PI or contact PD/PI if a multiple PD/PI model is used
4. Name of the individual with the FCOI
5. Name of the entity with which the individual has a financial conflict of interest
6. Reason(s) for the review
7. Methodology used for the review (e.g., methodology of the review process, selection of the review panel, support materials reviewed)
8. Findings of the review
9. Conclusions of the review

ASGCT will update previously submitted FCOIs (if applicable) to document the actions taken to manage the FCOI. ASGCT will notify the funder if bias is found and submit a mitigation report that includes the information above as well as a description of the impact of the bias on the research project and ASGCT's plan of action(s) 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). ASGCT may determine that additional interim measures are necessary regarding the individual's participation in the PHS-funded research project between the date that the financial conflict of interest or the individual's noncompliance is determined and the completion of the university's retrospective review.

If an individual fails to comply with this policy or a management plan and the noncompliance appears to have biased the design, conduct or reporting of the PHS-funded research, ASGCT will notify the funder of the corrective action taken or to be taken and will ensure compliance with the requirements for retrospective review and prepare a mitigation report, as applicable, for submission to the funding agency as required under 42 CFR Part 50, Subpart F. The funder may take its own action as it deems appropriate, which may include suspension of funding, or additional action by the ASGCT to maintain the objectivity of the project.

NOTE ON CLINICAL RESEARCH

If the Department of Health and Human Services determines that a PHS-funded 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 individual with an FCOI that was not managed or reported by the ASGCT as required by the regulation, ASGCT will require the individual to disclose the FCOI in each public presentation of the results of the research, AND request an addendum to previously published presentations.

RECORDS AND PUBLIC DISCLOSURE

ASGCT will maintain all disclosure forms, training certifications, management plans, reports and all related records of actions taken with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the PHS as governed by 42 CFR Part 50 Subpart F, and from other dates specified in 45 CFR 75.361, where applicable.

ASGCT has posted this policy on the ASGCT public website in accordance with the PHS regulations. In addition, this policy allows for certain information concerning identified FCOIs held by individuals to be made available and publicly accessible. The information will:

- Include the minimum elements as provided in the regulation
- Be posted on the website or made available within five (5) calendar days of a written request
- Be updated, at least annually (website only but any response to a written request should include the updated information)
- Be updated, within sixty (60) days of a newly identified FCOI (website only but any response to a written request should include the updated information)
- Remain available for three years from the date the information was most recently updated