

**Aprea Therapeutics, Inc.**  
**Government Awards Financial Conflict of Interest Policy**  
**Adopted: September 28, 2023**

**PURPOSE:** Under this policy, Aprea Therapeutics, Inc. (the “Company”) strives to ensure that all work performed under Government Awards meets the highest standard of integrity and is free of any real or perceived conflicts of interest that could harm patients, the reputation of Aprea Therapeutics, Inc., the governmental agency providing the funding, and/or external partners. As Aprea Therapeutics, Inc. must comply with government regulations when making expenditures with Government Awards, this policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in Governmental Awards. It is intended to comply with the requirements of federal regulations, including, but not limited to, the conflict of interest regulations of the U.S. Department of Health and Human Services Public Health Service (“the PHS FCOI Rules”) as found in 42 CFR Part 50 Part F (Promoting Objectivity in Research) and 45 CFR Part 94 (Responsible Prospective Contractors); (collectively referred to as the “Financial Conflict of Interest Rules”).

**DEFINITIONS:**

***Conflict Management Plan:*** the document specifying the actions to be taken to manage a Financial Conflict of Interest, consistent with the Company’s obligations under 42 CFR 50.605(a) and 45 C.F.R. 94.5(a).

***External Partner:*** a consultant, subcontractor, or sub-recipient performing work under a Government Award who is not employed by Aprea Therapeutics, Inc.

***Government Award:*** government grants, including research and other types of non-procurement financial assistance agreements (e.g., cooperative agreements, loans, loan guarantees, property, donated supplies, and direct appropriations) that Aprea Therapeutics, Inc. receives directly from government agencies or indirectly from pass through entities. (At Aprea Therapeutics, Inc., Government Awards are commonly referred to as “Sponsored Projects.”). Government Awards do not include procurement contracts, payments for health care services provided under government health care programs (e.g., Medicare, Medicaid) or Medical Education and Research Costs (MERC)).

***Financial Conflict of Interest (FCOI):*** a significant financial interest that could directly and significantly affect the design, conduct, or reporting of a research study or other government funded project (see 42 C.F.R. 50.603 and 45 C.F.R. 94.3).

***Immediate Family Member:*** a spouse, domestic partner, child or step-child, parent or step-parent, or sibling or step-sibling.

***Investigator:***

(1) For PHS-funded research: 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 (see 42 C.F.R. 50.603 and 45 C.F.R. 94.3).

(2) For other Government Awards: project staff directly involved in management of the project or who hold key responsibilities on the Government Award. Typically, these would be individuals specifically named to a Government Award or whose participation is key to the success of the project.

***Institutional Responsibilities:*** An Investigator's professional responsibilities on behalf of Aprea Therapeutics, Inc., which may include, but is not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards (see 42 C.F.R. 50.603 and 45 C.F.R. 94.3).

***Public Health Service (PHS):*** a division of the Department of Health and Human Services, consisting of the following agencies: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).

***Research:*** 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.

***Remuneration:*** salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships).

***Significant Financial Interest ("SFI"):*** Consistent with 42 C.F.R. 50.603 and 45 C.F.R. 94.3, any of the conflicts below constitute "significant financial interests":

(1) A financial interest consisting of one or more of the following interests of the Investigator or their Immediate Family Member that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(i) the value of any remuneration received from a public 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;  
or

(ii) the value of any remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or their immediate family) 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 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. The disclosure will include, at a minimum, the following details: (i) the purpose of the trip; (ii) the identity of the sponsor/organizer; (iii) the destination; and (iv) the trip duration. (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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.)

(3) A significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by Aprea Therapeutics, Inc. to the Investigator if the Investigator is currently employed or otherwise appointed by Aprea Therapeutics, Inc.;
- Intellectual property rights assigned to Aprea Therapeutics, Inc. and agreements to share in royalties related to such rights;
- 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; and
- Income from service on advisory committees or review panels for a federal, state, or local government agency, or an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

### **POLICY:**

It is the policy of Aprea Therapeutics, Inc. to comply with the Financial Conflict of Interest Rules (“FCOI Rules”) to ensure that the work performed under Government Awards is carried out in a manner that is free from any bias which may result from financial conflicts of interest. All Investigators for Government Awards must disclose any Significant Financial SFI to Aprea Therapeutics, Inc. Investigators must complete or update a disclosure survey at least annually during the period of the award and must disclose any new SFI’s within thirty days of

discovering or acquiring the SFI. Investigators also must ensure that the disclosure survey is completed or updated no later than the time of application for a Government Award.

If Aprea Therapeutics, Inc. determines that a SFI constitutes a Financial Conflict of Interest (“FCOI”), Aprea Therapeutics, Inc. will establish and monitor a Conflict Management Plan (“CMP”) to manage or eliminate the conflict of interest. The manager of Sponsored Projects Administration (“SPA”) will be the conflict of interest official responsible for managing the conflict of interest process for Government Awards. No Government Award funds may be expended unless the SPA Manager has determined that no FCOI exists or that any FCOI is manageable in accordance with the terms of a CMP that has been adopted and implemented in accordance with the procedures set forth in this policy.

### ***Duty to Cooperate***

If the conflict of interest official requests additional information from an Investigator to assess whether a SFI constitutes a Financial Conflict of Interest, (including but not limited to documents relating to the SFI), the Investigator must cooperate with the request. If a CMP is implemented in connection with a SFI, the Investigator must comply with the CMP. Compliance with the requirements of this policy is a condition of employment with Aprea Therapeutics, Inc. for employed Investigators and a condition of participating in Government Award projects as an External Partner. Failure to comply may result in appropriate sanctions.

### ***Education***

Investigators must complete training regarding this policy and the applicable regulations at the following times: (i) upon becoming an Investigator for Aprea Therapeutics, Inc.; (ii) before performing work under a Government Award; (iii) when this policy is revised to alter the responsibilities of an Investigator; (iv) and at least every four years.

### ***Public Posting of Policy***

This policy is posted for the publicly accessible website for Aprea Therapeutics, Inc. at [www.aprea.com](http://www.aprea.com).

### ***Reporting of Financial Conflicts of Interest for PHS-Funded Projects***

Before the expenditure of any funds under a PHS-funded project and within sixty days of subsequently identifying a Financial Conflict of Interest, the SPA Manager will report all Financial Conflicts of Interest that have not been eliminated to the PHS awarding component and will ensure that an appropriate Conflict Management Plan has been implemented. The report will include the elements required under the PHS FCOI Rules. For subsequently identified FCOI’s, the SPA Manager will conduct a retrospective review to determine whether the PHS-funded project was affected by the financial conflict of interest, and if bias is found, will submit a mitigation report to the PHS awarding component. The SPA Manager also will provide an annual FCOI report that addresses the status of any previously reported FCOI’s and CMP’s related to an ongoing PHS-funded project.

## ***External Partners***

Any individual or organization acting as a consultant, subcontractor, or subrecipient (“External Partner”) to Aprea Therapeutics, Inc. on a PHS-funded award must either: (1) have a FCOI policy that meets the requirements of the PHS FCOI Rules or (2) follow this policy.

- Organizations with their own policy will certify that the policy meets the requirements of the PHS FCOI Rules by submitting an External Partner Financial Conflict of Interest Disclosure form or registering with the FDP Clearinghouse at <https://fdpclearinghouse.org/> before submission of the Government Award. The SPA Manager will verify registration with the FDP Clearinghouse before submission. The contract with Aprea Therapeutics, Inc. will contain language requiring compliance with the organization’s FCOI Policy.
- Individuals and organizations without their own FCOI policy are required to follow this policy. The contract with Aprea Therapeutics, Inc. will contain language requiring compliance with Aprea Therapeutics, Inc.’s Government Awards FCOI Policy.

## **Procedure**

This procedure is for use by Aprea Therapeutics, Inc. employees and External Partners that do not have their own FCOI policy.

1. Before the expenditure of funds under a Government Award, Investigators must complete the training on Aprea Therapeutics, Inc.’s Government Awards FCOI Policy. All external investigators must complete FCOI training required under the policy. Training can either be completed using the NIH FCOI tutorial found at: <https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> or CITI COI training found at: <https://about.citiprogram.org/en/homepage/>.
2. Training must be documented by submitting the Government Award FCOI Training Certification form to Aprea Therapeutics, Inc. Sponsored Projects Administration. The required training is valid for four years; however, Investigators are required to certify annually that they understand and have complied with their responsibilities under Aprea Therapeutics, Inc.’s Government Awards FCOI Policy.
3. After the training is completed, the Investigator will complete the Government Award FCOI Questionnaire. This survey must be completed no later than the time of application for a Government Award and before any funds are expended. It also must be updated as required by the policy.
4. The principal investigator/project director will complete the Government Award Approval form, which requires verification that those meeting the definition of Investigator and External Partners have been informed of the requirement to comply with this policy.
5. The Investigator must report and update their Government Award FCOI Questionnaire when he/she is a recipient of sponsored travel. The Investigator will disclose: the purpose of the trip; the name of the entity that paid for the travel; the travel destination;

the duration of the trip; the dates of the travel; and if known, the approximate value of the Sponsored Travel.

6. If the SPA Manager determines a FCOI exists, he/she will create a draft CMP. The draft CMP will be presented to the Research Compliance Oversight Committee (RCOC) for consideration and approval. The RCOC will act as the Conflict of Interest Committee for purposes of Government Awards.
7. The actions taken by the RCOC will be documented in the RCOC meeting minutes. The SPA Manager will ensure that CMP's are properly implemented and will monitor compliance with CMP's on an ongoing basis. The RCOC will review the status of established CMP's at intervals determined by the RCOC and indicated in the CMP, and will have oversight responsibility for the enforcement of CMPs and compliance with this policy.
8. Each Investigator under a CMP must comply fully and promptly with the CMP, and each person identified in the CMP as having responsibility for monitoring compliance with the CMP must carefully and fully monitor that compliance.
9. For PHS-funded projects, SPA will disclose the FCOI and CMP to the PHS awarding component before the expenditure of any federal funds.
10. For PHS-funded projects, Aprea Therapeutics, Inc. will make FCOI information available to those who submit a request by sending an email to [john.hamill@aprea.com](mailto:john.hamill@aprea.com) or by writing SPA at the address below. Responses will be sent within five business days.
11. Aprea Therapeutics, Inc. will keep records related to FCOI and the related CMP for the longer of at least three years after:
  - a. the date of creation;
  - b. the date of termination or completion of the Government Award and submission of the final expenditure report for the Government Award identified in the disclosure statement;
  - c. the date of final resolution of any investigation, audit, or similar action involving the records; or
  - d. the date required to be in compliance with Aprea Therapeutics, Inc.'s Record Retention policies.
12. RCOC will regularly evaluate compliance with this policy and will review the effectiveness of SPA's conflict of interest management program, including a review of the implementation and effectiveness of these procedures.

### **SPA Procedure for External Partners with their own PHS Rule policy**

1. The principal investigator/project director will complete the Government Award Approval form, which requires them to inform any External Partner if they need to comply with FCOI Rules.
2. Prior to any application submitted by Aprea Therapeutics, Inc. for a Government Award, SPA must receive confirmation the External Partner has a FCOI policy that meets the PHS FCOI Rules.
3. The External Partner will have two options to verify they have a FCOI:
  1. Register with the FDP Clearinghouse, <https://fdpclearinghouse.org/>. At this time, this website is acting as a central registration location for many colleges. Aprea

Therapeutics, Inc. will accept this method of verification. Registration is free and you may contact SPA if you have questions.

2. Submit the External Partner Financial Conflict of Interest Disclosure.

Contact information:

Manager, Sponsored Projects Administration

Aprea Therapeutics, Inc.

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Phone: 617-463-9385

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