

## **CALAGEN BIOSCIENCES, LLC**

### **FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY**

#### **PURPOSE**

Calagen Biosciences, LLC is committed to the highest standards in research and scholarly activities and this policy is developed to safeguard the research integrity at the Company and to ensure that all work performed under government awards complies with federal regulations. The policy documents the requirements, responsibilities and strategies at Calagen Biosciences, LLC in identifying and managing financial conflicts of interest, as defined in the 2011 Revised Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F). The FCOI policy applies to any investigator engaging in research projects that are funded by government agencies. Through this policy, Calagen Biosciences intends to protect the design, conduct, interpretation, and reporting of the sponsored research from any bias due to financial conflicts.

#### **DEFINITIONS**

**1. Health and Human Services (HHS):**

The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

**2. Public Health Service (PHS):**

The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

**3. PHS Awarding Component:**

The organizational unit of the PHS that funds the research.

**4. Institution:**

Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

**5. Institutional Responsibilities:**

An investigator's professional responsibilities on behalf of the institution, and as defined by the institution in its policy on financial conflicts of interest, which may include activities such as research, research consultation, and professional practice.

**6. Investigator:**

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.

**7. PD/PI:**

Project director or principal Investigator of a PHS-funded research project.

**8. Senior/Key Personnel:**

The PD/PI and any other person identified as senior/key personnel by the institution in the grant application, progress report, or any other report submitted to the PHS by the institution.

**9. External Partner:**

A consultant, subcontractor, or sub-recipient performing work under a Government Award who is not employed by Calagen Biosciences, LLC.

**10. Government Award:**

Government grants and cost reimbursement contracts including research grants or contracts, and other types of government financial assistance (e.g., cooperative agreements, loans, loan guarantees, property, donated supplies, and direct appropriations).

**11. 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. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). For example, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

**12. Financial Interest:**

Anything of monetary value, whether or not the value is readily ascertainable.

**13. Significant Financial Interest (SFI):**

A financial interest consisting of one or more of the following interests of the PHS Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- (1) With regard to any publicly traded entity, an 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); 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
- (2) 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); or
- (3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income during the previous 12 months that exceeds \$5,000 for such rights and interests.

(4) Travel: The occurrence of any sponsored or reimbursed travel.

The term SFI does not include the following types of financial interests: salary, royalties, or other remuneration paid by the institution to the Investigator if the investigator is currently employed or otherwise appointed by the institution, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights; any ownership interest in the institution held by the investigator, if the institution is a commercial or for-profit organization; 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 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; 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.

**14. Financial Conflict of Interest (FCOI):**

An SFI that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

**15. FCOI Regulation:**

FCOI regulation refers to 42 CFR Part 50 Subpart F, Promoting Objectivity in Research, which applies to both grants and cooperative agreements.

**16. FCOI Management:**

Taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**17. Disclosure of SFIs (or SFI Disclosure):**

An investigator's disclosure of SFIs to an institution.

**18. FCOI Report:**

An institution's report of an FCOI to a PHS Awarding Component.

**19. Small Business Innovation Research (SBIR):**

A program for small businesses that is established by the Awarding Components of the PHS and certain other federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended.

**20. Small Business Technology Transfer Program (STTR):**

A program under which a portion of a federal agency's extramural research or research and development effort is reserved for award to small business concerns for cooperative research and development.

**TRAINING**

All investigators engaging in a PHS-funded project are required to complete FCOI training as required by the funding agency. Training will be performed using the following online course: NIH Financial Conflict of Interest tutorial (web address: [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)). This course was designed by the National Institutes of Health (NIH) to provide training and a reference guide for NIH FCOI policies. Upon completion of the training, each investigator needs to answer the review questions to obtain a certificate of completion and submit the completion record to the CEO of the company. This training is required for every individual prior to engaging in any PHS-funded research activities, at least every three years, and when any of the following happens:

- (1) If there is any change to the company's FCOI policies or procedures.
- (2) A new investigator joins the research team.
- (3) The company discovers that an investigator is not in compliance with the policy or has failed to comply with a management plan designed to mitigate an FCOI.

## **PROCEDURE**

### **A. Disclosure of SFIs**

Each investigator shall disclose SFIs that are reasonably believed to be related to the investigator's company responsibilities. The financial interests that are relevant include those of the investigator, the investigator's spouse and dependent children. The investigator shall disclose SFIs at the following times:

- (1) Initial disclosure: Prior to submitting an application for funding, as required by the funding agency.
- (2) In addition, each investigator must update his/her disclosure of SFIs throughout the entire period of PHS support:
  - within 30 days of discovering or acquiring a new SFI.
  - at least annually.
- (3) New investigators must disclose their SFIs before joining an ongoing PHS-funded research project.

Each investigator having an SFI that requires disclosure under the FCOI policy shall complete the **Significant Financial Interest (SFI) Disclosure Form** and submit it to the CEO for review.

### **B. Review and Management of SFIs**

After receiving the SFI Disclosure Form from an investigator, the CEO will determine whether an investigator's SFI is related to the research and whether it is an FCOI. If it is concluded that there is a potential conflict of interest, a management plan will be put in place to address the issue. Possible solutions to manage, reduce or eliminate an FCOI include, but are not limited to:

- (1) Disclosure of SFIs when presenting or reporting the research discoveries.
- (2) Changing the research plan.
- (3) Appointment of an independent reviewer(s) to ensure the design, conduct, interpretation and reporting of the research free from bias resulting from the SFIs.
- (4) Divestiture of the SFIs or severance of relationships that create the FCOI (or FCOIs).
- (5) Replacement of the individual(s) with FCOIs with other investigator(s), if possible, on the funded research project.
- (6) For research involving human subjects, disclosure of FCOIs directly to research participants.

All management plans are required to be signed by the investigator and the CEO. Compliance of the management plan shall be monitored by the CEO on an ongoing basis until the completion of the funded project.

### **C. Subrecipients and Cooperative Agreements**

Collaborators from other institutions may share responsibility for the design, conduct or reporting of PHS-funded research and receive subawards from Calagen Biosciences, LLC. They are award subrecipients and are expected to comply with the FCOI policies and procedures of the institutions that they are affiliated with. In the collaboration agreement, the subrecipient institutions shall certify that they will take the responsibility to review SFI disclosures. If any FCOI is found, they will develop a mitigation plan to manage the FCOI according to PHS regulations (42 CFR, Part 50, subpart F), as well as notify Calagen Biosciences within 30 days of such identification. If such certification (or assurance) is not available from the subrecipient institutions, the subaward agreement shall specify that the subrecipients complete their SFI disclosures to Calagen Biosciences. The time period(s) shall give Calagen Biosciences sufficient time to comply with its review, management and reporting obligations to the funding agency.

If a collaborator engages in research under an independent consulting agreement with Calagen Biosciences, the collaborator must complete the SFI Disclosure Form of Calagen Biosciences. If any FCOI is identified, he/she is expected to comply with an SFI management plan to mitigate the FCOI.

### **D. Failure to Disclose or Noncompliance**

All investigators at Calagen Biosciences are expected to comply with the company's FCOI policy. When an SFI is not disclosed in a timely manner by an investigator, the PI of the PHS-funded project or the CEO of the Company shall request the investigator submit his/her SFI Disclosure Form within thirty days. Within sixty days, the CEO shall review the SFI Disclosure Form and determine whether an FCOI exists; and if an FCOI is identified, a management plan shall be established to mitigate the FCOI as required by this policy and the PHS regulation.

If a potential FCOI exists and the employee fails to disclose it truthfully, both the PI of the research project and the CEO of the Company shall be notified. The CEO shall contact the investigator and request that a formal disclosure of the potential FCOI be made.

Failure of compliance with the company's FCOI policy may result in sanction or disciplinary actions against the violating individual. Possible sanctions include, but are not limited to, the following:

- (1) Letter of warning or admonishment.
- (2) Suspension or termination of the individual's research activities related to the awarded project.
- (3) Demotion or removal from assigned company roles.
- (4) Suspension or termination of individual's employment.
- (5) For consultants and subrecipients, failure to comply with the appropriate FCOI policy or PHS regulation may result in the agreement to be terminated for cause.
- (6) In addition, PHS rules may require that any violations of federal regulations be reported to the federal sponsor.

### **E. Maintenance of Records**

Calagen Biosciences, LLC will maintain all records relating to the investigators' SFI Disclosure Forms and the actions taken by the Company for FCOI management for at least

three years from the date that the final expenditures report is submitted to the awarding agency, or from other dates specified in 45 CFR 75.361 (Retention Requirements for Records) for different situations.

#### **F. Reporting of FCOIs for PHS-Sponsored Research**

The CEO of the Company is responsible for reporting the investigators' disclosures of SFI and the corresponding management plans to the PHS sponsor. Reporting is required at the following times:

- (1) Initial report: Prior to the expenditure of any funds for the research project, the Company must provide to the PHS sponsor an FCOI report regarding any investigator's SFI identified to be an FCOI and the corresponding management established according to the PHS rules and the funding agency's requirements.
- (2) When an SFI is identified as an FCOI after the initial FCOI report, the Company shall submit, within sixty days, an FCOI report regarding the new FCOI. If an FCOI was not disclosed timely, the Company shall submit an FCOI report to the funding agency within 60 days of the discovery, as well as complete a retrospective review to determine whether any bias has occurred to the funded research that was conducted prior to the identification and management of the FCOI. In addition, if bias is found, the Company shall promptly notify and submit a mitigation report to the PHS sponsor.
- (3) Annual FCOI report: For any ongoing research where an FCOI was previously reported to the PHS sponsor, the Company shall provide an annual FCOI report that addresses the status of the FCOI and any changes to the management plan.

#### **G. Exclusions**

PHS regulations exclude applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs from FCOI disclosure requirements.

#### **PUBLIC ACCESSIBILITY**

This policy will be posted on the company's website (<http://www.calagenbio.com>). For research projects funded by PHS, Calagen Biosciences, LLC will make the FCOI information of relevant investigators available if a request is received at the following email address:

[huataog@calagenbio.com](mailto:huataog@calagenbio.com).

## Significant Financial Interest (SFI) Disclosure Form

### Who must disclose?

The FCOI policy of Calagen Biosciences, LLC requires that all investigators disclose their significant financial interests (SFIs) that are related to a sponsored research project. Investigator is defined in the policy as any individual serving as a Project Director, Principal Investigator, and any other person, regardless of title or position, who is responsible for the design, conduct, interpretation, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. Except for certain subrecipients, whose employing institutions take the responsibility for the disclosure and management of their SFIs, all investigators must complete this form and submit it to the Chief Executive Officer.

### Part I. Investigator completing this form:

Name:

Title:

Department:

Institution (Calagen or subrecipient):

### Part II. Project title:

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### Part III. Principal investigator(s):

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### Part IV. Check the one that applies:

\_\_\_\_\_ Initial FCOI Disclosure: Prior to any expenditure of the fund

\_\_\_\_\_ Update Disclosure: Within 30 days after acquiring (or discovering) an SFI during an award period

\_\_\_\_\_ Annual report: Annual update of SFIs

### Part V. Indicate whether you have any SFIs related to the sponsored research project:

\_\_\_\_\_ I (and/or my spouse or dependent children) have no SFI related to the project award (stop; sign and submit the Disclosure Form to the CEO).

\_\_\_\_\_ I (and/or my spouse or dependent children) do have SFI(s) related to the project award (continue to complete the rest of this Form)

### Part VI. Describe each SFI (please use additional pages if necessary):

A. Entity name and location:

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B. Nature of the SFI:

\_\_\_\_\_ I (and/or my spouse or dependent children) have equity or stocks in this publicly-traded entity in the following estimated amount:

Dollar amount: \$ \_\_\_\_\_  
(or Percentage: \_\_\_\_\_%)

\_\_\_\_\_ I (and/or my spouse or dependent children) have equity or ownership in this privately-held entity:

Dollar amount: \$ \_\_\_\_\_  
(or Percentage: \_\_\_\_\_%)

\_\_\_\_\_ I (and/or my spouse or dependent children) received or will receive licensing fees and royalties from intellectual property (patents and copyrights) from this entity:

Dollar amount: \$ \_\_\_\_\_

\_\_\_\_\_ I (and/or my spouse or dependent children) receive salary, consulting fees, advisory board fees, honoraria, gifts, or any other compensation from this entity:

Dollar amount: \$ \_\_\_\_\_

\_\_\_\_\_ I (and/or my spouse or dependent children) serve in a fiduciary role for this entity:

Dollar amount: \$ \_\_\_\_\_

\_\_\_\_\_ I (and/or my spouse or dependent children) was reimbursed or sponsored to travel by this entity:

Dollar amount: \$ \_\_\_\_\_

\_\_\_\_\_ I (and/or my spouse or dependent children) receive (or received) other compensations that could be affected by the outcome of this research:

Dollar amount: \$ \_\_\_\_\_

C. Please describe how the outcome of the project award may influence the SFI(s):

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D. Do you think that your SFI(s) will affect your unbiased performance on the sponsored project(s) (for example, the design, conduct, interpretation, or reporting of the research project)? Please explain.

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**Part VII.** In addition to completing this form, each investigator is required to complete the online FCOI training (as specified in the policy): NIH Financial Conflict of Interest tutorial (web address: [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)). A certificate of completion shall be submitted to the CEO of the Company. If you have any further questions regarding the Form or the training, please contact the Principle Investigator of the sponsored project or the CEO of the Company.

**Part VIII.** For each investigator, please sign below to certify that you have answered all the questions in the Form completely and truthfully. Failure to do so may result in disciplinary actions from the Company or PHS.

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date