

# **Senti Biosciences, Inc. Financial Conflict of Interest Policy For Research Performed under Public Health Services Funding**

## **A. Persons covered by this policy**

This policy applies to all personnel, including full-time and part-time employees, and contingent workers of Senti Biosciences, Inc. who are planning to participate or are participating, as an Investigator in a Research performed under PHS grants, cooperative agreements or other funding agreement, excluding any Research performed under any SBIR Program Phase I applications.

## **B. Purpose**

The purpose of this policy is to promote objectivity in Research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of Research funded under PHS grants, cooperative agreements, or other funding agreements will be free from bias resulting from Investigator financial conflicts of interest and to comply with relevant federal regulations, including 42 C.F.R, 50 Subpart F "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought" and 45 CFR Part 94 "Responsible Prospective Contractors".

## **C. Definitions**

1. *"Company"* means Senti Biosciences, Inc.
2. *"Company designated official(s)"* means any person or persons (e.g. a committee) designated by Company and communicated Company-wide as having been designated to serve in such capacity to perform such responsibilities to be performed by a Company designated official(s) under this policy.
3. *"Company Responsibilities"* means any activity conducted by Investigator on behalf of Company as an employee, contingent worker, consultant, collaborator, as the case may be.
4. *"Disclosure"* means an Investigator's disclosure of SFIs to Company.
5. *"FCOI Report"* means Company's report of an FCOI to a PHS Awarding Component.
6. *"Financial Conflict of Interest" or "FCOI"* means any SFI that could directly and significantly affect the design, conduct, or reporting of PHS-funded Research.
7. *"Financial Interest"* means anything of monetary value, whether or not the value is readily ascertainable.
8. *"HHS"* means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

9. "*Investigator*" means the project manager, 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 PHS, or proposed for such funding, which may include, for example, collaborators, subcontractors, or consultants.
10. "*Manage*" means 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.
11. "*Management Plan*" means suitable action plan to eliminate or Manage the FCOI consistent with the objectives of this policy.
12. "*PHS*" means the Public Health Services of the U.S. Department of Health and Human Services, and any components of the Public Health Services to which the authority involved may be delegated, including the National Institute of Health (NIH).
13. "*PHS Awarding Component*" means the organizational unit of PHS that funds the grant, cooperative agreement, or other funding agreement pertaining to the applicable PHS-funded Research.
14. "*PD/PI*" means a project director or principal investigator of a PHS-funded Research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.
15. "*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 and product development. The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Company training grant, program project, or research resources award.
16. "*Senior/key personnel*" means the PD/PI and any other person identified as senior/key personnel by Company in the grant application, progress report, or any other report submitted to PHS by Company in compliance with the requirements of the applicable PHS Awarding Component for the PHS-funded Research.
17. "*Significant Financial Interest*" or "*SFI*" means:
  - a. A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Company Responsibilities:
    - (i) 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;

- (ii) 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
  - (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- b. Payment for Travel:
- (i) 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 Company Responsibilities; 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
  - (ii) Disclosure for travel shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Company will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded Research.
- c. Exclusions: The term Significant Financial Interest does not include the following types of Financial Interests:
- (i) Salary, royalties, or other remuneration paid by Company to the Investigator if the Investigator is currently employed or otherwise appointed by Company, including intellectual property rights assigned to Company and agreements to share in royalties related to such rights;
  - (ii) Any ownership interest in Company held by the Investigator, as long as Company is a commercial or for-profit organization;
  - (iii) 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;
  - (iv) 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; or
  - (v) Income from service on advisory committees or review panels for 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.

*18. Small Business Innovation Research (SBIR) Program* means the extramural research program for small businesses that is established by the PHS Awarding Components and certain other Federal agencies under the Small Business Innovation Development Act, as amended, and includes the Small Business Technology Transfer (STTR) Program.

#### **D. Responsibilities**

1. Training:
  - a. Each Investigator shall complete the FCOI training provided by Company prior to engaging in Research under any PHS-funded grant, which training will cover information on this policy, Investigator's Disclosure responsibilities, and the applicable Federal regulations.
  - b. Each Investigator is required to complete such training at least once every four years and immediately when any of the following circumstances apply:
    - (i) If Company revises this policy in a manner that affects the requirements or responsibilities of the Investigator;
    - (ii) An Investigator is new to Company; or
    - (iii) Company finds that an Investigator is not in compliance with this policy or any Management implemented in accordance with this policy.
2. Disclosure:
  - a. Any Investigator who is planning to participate or is participating in a PHS-funded Research shall disclose to Company a designated official(s), Investigator's SFI (and those of the Investigator's spouse and dependent children) as stated in this policy.
  - b. Each Investigator shall keep the Company designated official(s) informed of the Investigator's SFI. If a Company designated official(s) becomes aware of a conflict of interest that an Investigator has not disclosed, the Company designated official(s) shall discuss the situation with the Investigator, and require that a written Disclosure be made as provided in this policy.
  - c. For any Investigator who is planning to participate in a new PHS-funded Research, such Investigator must Disclose Investigator's SFI (and those of the Investigator's spouse and dependent children) no later than at the time of application for the applicable PHS-funded Research.
  - d. For any new Investigator who is planning to participate in an ongoing PHS-funded Research, such Investigator must Disclose Investigator's SFI (and those of the Investigator's spouse and dependent children) prior to such Investigator's participation in any such ongoing PHS-funded Research.
  - e. For any Investigator who is participating in an existing PHS-funded Research,
    - (i) Such Investigator must make an updated Disclosure of SFI (and those of the Investigator's spouse and dependent children) annually to Company during the period of the applicable award. If no SFI is present, Investigator must submit a Disclosure that states "none". Company designated official(s) shall set and disseminate Company-wide the date when such annual Disclosure is due; and
    - (ii) Such Investigator must make a new or an updated Disclosure within thirty (30) days of discovering or acquiring a new SFI.
3. Review and Management:
  - a. Company designated official(s) shall solicit and review Disclosures from any Investigators (and those of the Investigator's spouse and dependent children) who are planning on participating or are participating in a PHS-funded Research to determine

- (i) If the SFI of the Investigator (and those of Investigator's spouse and dependent children) is related to the PHS-funded Research; and
  - (ii) If so related, whether the SFI is an FCOI.
- b. An SFI is related to a PHS-funded Research when Company's designated official(s) reasonably determines that the SFI
    - (i) Could be affected by the Research; or
    - (ii) Is in an entity whose Financial Interest could be affected by the Research.
- c. An FCOI exists when Company designated official(s) reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research.
- d. If a determination is made that an FCOI exists, then Company designated official(s) shall seek input from the Investigator and recommend to the Chief Scientific Officer (or any other executive designated by Company to be responsible for such oversight), or to the Chief Operating Officer in the event that the FCOI results from the SFI of the CSO, a Management Plan to Manage the FCOI consistent with the objectives of this policy. The Management Plan shall provide for its periodic review and updating at least annually. In the event that there is no reasonable way to manage an FCOI, then the Investigator may be prohibited from participating in the related PHS-funded Research until such a time as the FCOI is eliminated. Examples of conditions or restrictions that might be imposed to Manage a FCOI include, but are not limited to:
    - (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the related PHS-funded Research);
    - (ii) For PHS-funded Research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
    - (iii) 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;
    - (iv) Modification of the research plan;
    - (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the related PHS-funded Research;
    - (vi) Reduction or elimination of the Financial Interest (e.g. sale of an equity interest); and
    - (vii) Severance of relationships that create the FCOI.
- e. The Chief Scientific Officer, or the Chief Operating Officer in the event that the FCOI results from an SFI of the CSO, (or any other executive designated by Company to be responsible for such oversight) shall review the proposed Management Plan and can approve, modify and approve, or return to Company designated official(s) for additional work. If a Management Plan is implemented under this policy, Company shall monitor the Investigator's compliance of the Management Plan on an ongoing basis until the completion of the PHS-funded Research project.
  - f. The review of any SFI, determination of FCOI, and implementation of any Management Plan by Company for any FCOI shall be completed:
    - (i) Prior to Company's expenditure of any funds under the PHS-funded Research project in the case of a Disclosure by an Investigator planning to participate in a new PHS-funded Research; and

- (ii) Within sixty days of such Disclosure in the case of a Disclosure by an Investigator who is new to participating in an ongoing PHS-funded Research or an updated Disclosure by an existing Investigator.

#### **E. Violations and Sanctions**

1. **Sanctions:** Violations of Company policies, including the failure to avoid a prohibited activity or disclose an SFI in a timely manner, will be dealt with in accordance with applicable policies and procedures that may include disciplinary actions up to and including termination of employment.
2. **Clinical Research:** In any case in which the HHS 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 Investigator with an FCOI that was not Managed or reported by Company as required by this policy, Company designated official(s) shall require the Investigator involved to disclose the FCOI in each public presentation of the results of such Research and to request an addendum to previously published presentations.
3. **Retrospective Review:** In addition, if Company designated official(s) determines that an FCOI was not identified or Managed in a timely manner including failure by the Investigator to Disclose an SFI that is determined by Company to constitute an FCOI; failure by Company to review or Manage such FCOI; or failure by the Investigator to comply with an FCOI Management Plan, Company shall, within one hundred twenty (120) days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research. Company will document the retrospective review, and such documentation shall include the following key elements: project number; project title; name of PI; name of the Investigator with the FCOI; name of the entity with which the Investigator has an FCOI; reason(s) for the retrospective review; detailed methodology used for the retrospective review; findings of the review; and conclusions of the review. Based on the results of the retrospective review, if appropriate, Company designated official(s) shall update the previously submitted FCOI Report, specifying the actions that will be taken to Manage the FCOI going forward. If bias is found, Company must notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Company's plan of action or actions taken to eliminate or mitigate the effect of the bias.

#### **F. Company Reporting**

1. Company, shall provide annual and revised reports of FCOIs to the applicable PHS Awarding Component per the applicable regulations:
  - a. Prior to the expenditure of any funds under a PHS-funded Research project;
  - b. Within sixty (60) days of identification for an Investigator who is newly participating in the project;

- c. Within sixty (60) days for new or newly identified FCOIs for existing Investigators;
  - d. At least annually (at the same time as when Company is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the Management Plan, if applicable, until the completion of the project; and
  - e. Following retrospective review to update a previously submitted report, if appropriate.
2. Company, through its Company designated official(s), shall notify the applicable PHS Award Component of bias found in the design, conduct, or reporting of the applicable PHS-funded Research including whether Investigator failure to comply with this FCOI policy or Management Plan appears to have caused such bias. In the event bias is found, Company will submit a mitigation report in accordance with the regulation. The mitigation report must include, at a minimum, a description of the impact of the bias on the Research project and the Company'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).
3. FCOI records shall be maintained for at least three (3) years from the submission of the final expenditure reports for the pertinent PHS-funded Research or longer as required by other policy or regulation.

#### **G. Subrecipients**

If Company carries out the PHS-funded Research through a subrecipient, Company shall take reasonable steps to ensure that such subrecipient Investigator complies with pertinent FCOI requirements as mandated by PHS regulation. Company shall incorporate into a written agreement with the subrecipient the terms that establish whether this policy or the FCOI policy of the subrecipient will apply to the subrecipient Investigator, and if subrecipient's FCOI policy applies to subrecipient's Investigators, such written agreement shall :

1. Require the subrecipient to certify that the subrecipient's FCOI policy complies with this policy and the regulation, or agree in writing that the subrecipient Investigators are subject to this policy for disclosing SFI that are directly related to the subrecipient's work for Company;
2. Specify the time period(s) for the subrecipient to report all identified FCOIs to Company with sufficient time to enable Company to timely provide FCOI Reports to the PHS Awarding Component as required by this policy; and
3. Specify the time period(s) for the subrecipient to submit all subrecipient Investigator Disclosures of SFIs to Company with sufficient time to enable Company an opportunity for Company to timely comply with its review, management, and reporting obligations under the regulations.

#### **H. Public Accessibility Requirement**

1. Company shall post this FCOI policy on the Company public website, as required by the regulation.

2. FCOI informational requests by the public concerning identified FCOIs held by senior/key personnel should be made to the Chief Scientific Officer. The Chief Scientific Officer shall respond to requests for FCOI information within five (5) business days with minimum reporting elements as provided for under applicable regulations.