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Deltos Inc. Financial Conflict of Interest Policy for Research Supported by The National Institutes of Health

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of Deltos' research funded by the National Institute of Health.

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A. Persons covered by this policy

This policy applies to all personnel, including all Members and full-time, part-time, temporary, and contract employees, of Deltos ("company") who are planning to participate in, or are participating in, National Institute of Health ("NIH") funded research by means of a grant or cooperative agreement. This policy applies to individuals who meet the regulatory definition of “Investigator” (as defined below) who are planning to participate in or who participate in PHS/NIH-funded research. The policy also applies to collaborators or consultants, as noted.

B. Preamble

1. The primary goal 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 NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.
2. This policy is implemented in accordance with 42 CFR Part 50 Subpart F - "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought," 45 CFR Part 94 - “Responsible Prospective Contractors”, which set requirements for promoting objectivity in Public Health Service (PHS)–funded research for grants, cooperative agreement, and research contracts, respectively. The regulations do not apply to SBIR or STTR Phase I applications or awards. This policy implements the regulatory requirements for PHS/NIH grants and cooperative agreements.

C. Statement of general policy

1. The design, conduct, and reporting of Research funded under NIH grants or cooperative agreements should be free from bias resulting from Investigator financial conflicts of interest.
2. To provide a reasonable expectation of achieving the goal of this policy, Investigators shall complete appropriate training as required under this policy; Investigators shall disclose significant financial interests (SFI) that are related to the Investigator’s institutional responsibilities at the time of application, annually and provide new or updated financial disclosures within 30 days of acquiring or discovering a new SFI; COMPANY shall determine if the SFI is related to the research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research) and if the SFI is a financial conflict of interest (i.e., the SFI is related to the research and could directly and significantly affect the design, conduct, or reporting of the NIH-funded research); provide for the management of Financial Conflicts of Interest; and COMPANY shall make reports or disclosures to both the NIH and to the public as required under this policy.
3. Nothing in this policy shall be construed to permit, even with disclosure, any activity that is prohibited by law.

D. Definitions

"Designated Official(s)" means the individual(s) appointed by the Company to solicit and review disclosures of significant financial interests, determine FCOIs in accordance with 42 CFR 50.604(f) and this policy, and develop management plans for identified FCOI.

Disclosure means an Investigator's disclosure of significant financial interests to the Company.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. Note: A Financial

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Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project (i.e., the Significant Financial Interest could be affected by the research or the Significant Financial Interest is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

FCOI Report means the Company's report of a Financial Conflict of Interest to a PHS Awarding Component.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

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.

Company means Deltos.

Company Responsibilities means an Investigator's professional responsibilities on behalf of the Company, and as defined by the Company in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, training, professional practice, and service on panels such as Institutional Review Boards or Data Safety and Monitoring Boards.

Investigator means 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, subcontractors, or consultants. The Company will consider the role, rather than the title, of those involved in the research and the degree of independence with which those individuals word when considering who meets the definition of "Investigator."

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Member means any person executing the Company Operating Agreement, or thereafter admitted to the Company as a Member as provided in the Company Operating Agreement.

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 under this subpart.

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).

PHS Funded research means any activity supported by a Public Health Service (PHS) Awarding Component through a grant, cooperative agreement, or contract, whether funded under the PHS Act or other statutory authority.

NIH means National Institutes of Health (NIH), the biomedical research agency within the Public Health Service (PHS) that funds and conducts research to improve health and advance scientific knowledge.

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. As used in this subpart, the term includes any such activity for which research funding is available from a NIH 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.

Senior/key personnel mean the PD/PI and any other person identified as senior/key personnel by the Company in the grant application, progress report, or any other report submitted to the PHS by the Company under the regulation. The term is defined only as it relates to the Public Disclosure requirements that require making certain information publicly available when FCOIs are identified for “senior/key personnel” as explained in Section I. below.

Significant Financial Interest means:

a) A domestic or foreign financial Interest consisting of one or more of the following interests of the Investigator, and those of the Investigator's spouse, domestic partner and dependent children that reasonably appears to be related to the Investigator's Company responsibilities (e.g., research, product and services development and testing, operations management, administration, etc.) performed on behalf of the Company, and that consists of one or more of the following:

i. With regard to 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;

ii. With regard to 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), or a management or governance position; or

iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income in excess of $5,000 related to such rights and interests.

Note: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institution of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000).

b) Reimbursed or Sponsored Travel:

i. Investigators also must disclose the occurrence of any foreign or domestic reimbursed or sponsored travel that exceeds $5,000 (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;

ii. provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency located in the United States, a United States 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 a United States Institution of higher education. Reimbursed or sponsored

travel received from a foreign government or a foreign institution of higher education is required to be disclosed if such income exceeds $5,000.

iii. Disclosure for travel shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The 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.

iv. The initial disclosure must include reimbursed or sponsored travel received over the previous twelve months. Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

c) Significant Financial Interests do *not* include:

i. Salary, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights.

ii. Any ownership interest in the Company held by the Investigator since the Company is a for-profit organization.

iii. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency located in the United States, a United States 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 a United States Institution of higher education.

iv. Income from service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, a United States 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 a United States Institution of higher education.

v. 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.

Note the Foreign Disclosure Requirements Related to the Exclusions: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received any foreign entity, including foreign Institution of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000).

E. Policy Implementation

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1. **Training Required**: Investigators shall complete FCOI training provided by the Company prior to engaging in NIH-funded research and then every four years thereafter. Training will be informed about the Company's policy, Investigator's SFI disclosure responsibilities and requirements per the policy, and the Federal regulation. Investigators will be required to complete the NIH FCOI training modules and provide a certificate of completion to the “COMPANY" representative. The "COMPANY" will retain a copy of the certification of completion of FCOI training for audit purposes. Immediate training will be required if the Company revises this policy in a manner that affects the Investigator, when an Investigator is new to the Company, or as a result of a finding of noncompliance with this policy or a management plan, or other related misconduct.

Training on the FCOI regulation will be provided to “Investigators” by utilizing the NIH training found at FCOI Training | grants.nih.gov or FINANCIAL CONFLICT OF INTEREST - NEWEST (nih.gov).

The Company also requires Investigators to review the NIH Virtual Seminar presentation on FCOI compliance from the following location:
https://www.youtube.com/watch?v=D292YZ6BX24

2. **Disclosure Requirement**:

a) An Investigator shall disclose any Significant Financial Interest as defined and provided for herein. Research should not be undertaken on pending applications where a Significant Financial Interest is present until a determination has been made and is managed pursuant to this policy.

b) Investigators shall keep their “Company” designated official(s) informed of the Investigator's Significant Financial Interest. If a designated official becomes aware of a significant financial interest that an employee has not disclosed, the supervisor shall discuss the situation with the employee, require that a written disclosure be made as provided in this policy, and inform the President to anticipate the receipt of a new Disclosure.

3. **Disclosure Frequency**:

a) Disclosure must be made no later than at the time of application for NIH-funded research.

b) Disclosure must be made annually to the designated official(s). If no Significant Financial Interest is present, a Disclosure must still be submitted that states "none”. The annual Disclosure due date is April 15th, and will be disseminated Company wide.

c) In addition to the annual Disclosure, a new or updated Disclosure must be completed in a timely manner whenever a new Significant Financial Interest arises or when a significant change occurs concerning an existing Disclosure.

d) In any event, an SFI Disclosure must be made within thirty (30) days of discovery or acquiring a new Significant Financial Interest.

e) Newly hired Investigators should make a Disclosure as part of their new hire employment process.

4. **Review and Determinations of FCOI**:

a) **Relatedness Test:** The designated official(s) shall solicit and review SFI Disclosures and determine if they are a FCOI. A Financial Conflict of Interest exists when the Company, through its designated official(s), reasonably determines that an Investigator’s Significant Financial Interest is related to a NIH-funded research project and constitutes and FCOI. The SFI is related to the NIH-funded research when:

i. the Significant Financial Interest could be affected by the research or

ii. the Significant Financial Interest in an entity whose financial interest could be affected by the research.

b) **Designated Official FCOI Determination**: If the SFI is determined to be related to the NIH-funded research, an FCOI exists when the designated official(s) determine the SFI could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

i. Members shall review SFI Disclosures and determine if they are a FCOI when required for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI.
ii. Members shall review SFI Disclosures and determine if they are a FCOI and implement a management plan within 60 days whenever the Company identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Company.

5. Management of SFIs that Pose an FCOI

a) If a determination is made that a FCOI exists, then the Members shall seek input from the Investigator and recommend to the President a suitable action plan ("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 a FCOI, then the Investigator may be prohibited from participating in the related Research until such a time as the FCOI is eliminated.

b) Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

i. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to staff members working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc.;
ii. For 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 financial conflict of interest;
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 research;
vi. Reduction or elimination of the financial interest (e.g. sale of an equity interest); or
vii. Severance of relationships that create financial conflicts
viii. The President shall review the proposed Management Plan and can approve, modify and approve, or return to the Members for additional work. Final review and determination must be completed prior to the expenditure of any PHS funds for the applicable Research.

6. Monitoring Investigator Compliance

The Company will monitor Investigator compliance with the management plan for the duration of the NIH award. Disclosure of FCOIs will be made in publications, presentations, and other communications. Investigators must also disclose the FCOI in writing to study personnel and provide a copy of this disclosure to the DO for recordkeeping.

F. Violations and Sanctions

1. Sanctions: Violations of Company policies, including the failure to avoid prohibited activity or disclose a Significant Financial Interest 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 Requirements: In any case in which the HHS determines that a NIH-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 a FCOI that was not managed or reported by the Company as required by this policy, the Members shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

G. Company Reporting

1. The Company, through its eRA Commons FCOI Module assigned FCOI Signing Official (SO) will provide annual and revised reports of FCOI to National Institutes of Health (NIH) via the eRA Commons FCOI Module:

a) Prior to the expenditure of funds under a new award;

b) within sixty days of identification for an Investigator who is newly participating in the project;

c) within sixty days for new or newly identified FCOIs for existing investigators;

d) at least annually (at the same time as when the 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;

e) following retrospective review to update a previously submitted report, if new information is discovered that was not previously reported to the NIH.

The NIH eRA Commons FCOI Module User Guide, available at the following location, provides instructions for preparing and submitting FCOI reports:
https://www.era.nih.gov/files/fcoi_user_guide.pdf

Types of FCOI Reports Summary Chart for NIH:

Required FCOI Reports to NIH via eRA Commons FCOI Module		
REPORT	**CONTENT**	**REQUIRED WHEN**
New FCOI Report (Initial submission)	Grant number; PI; name of entity with FCOI; nature of FCOI; value of the financial interest (in required increments); description of how the financial interest relates to the research; key elements of the management plan	Prior to the expenditure of funds on a new award; within 60 days of identifying any new FCOI during the award period.

Annual FCOI Report	Status of the FCOI (whether it is still being managed or no longer exists) and any changes to the management plan, if applicable.	Submitted annually at the same time as the annual progress report, multi-year progress report, or at the time of a grant extension.
Revised FCOI Report	If applicable, updates to a previously submitted FCOI report to describe actions that will be taken to manage the FCOI going forward or to revise the original report.	Following a retrospective review when noncompliance with the regulation is identified, if applicable.
Mitigation Report	Project number; project title; contact PI/PD; name of Investigator with FCOI; name of entity with FCOI; reason for review; detailed methodology, findings, and conclusions.	After a retrospective review when bias is found.

H. Actions Related to Noncompliance with the Policy

1. Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Company to constitute a Financial Conflict of Interest;
- Failure by the Company to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

the Company shall, within 120 days of the Company's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

The Company shall document the retrospective review which must include at least the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- Findings of the review; and
- Conclusions of the review.

2. The Company, through its Members, shall notify NIH of bias found in the design, conduct, or reporting of NIH 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, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., 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). If the FCOI was previously reported to the NIH, the mitigation report will be submitted as a "Revised FCOI Report." Thereafter, the Institution will submit FCOI reports annually as prescribed by the regulation.

I. Maintenance of Records

The Company will keep all records of all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest), and all actions under the Institution's policy or retrospective review, if applicable. The records of financial disclosures and any resulting action will be maintained by the Company for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations.

J. Subrecipients

Company, through its Members, shall require sub-recipient compliance with the FCOI requirements as mandated by PHS regulation:

a) If applicable, obtain a certification from the subrecipient that its FCOI policy complies with the regulation.

b) If applicable, include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the Company to report identified FCOIs to NIH as required by the regulation (i.e., prior to the expenditure of subrecipient funds and within 50-55 days of identifying an FCOI during the period of an award) to allow the Company to report the FCOI to the NIH as required by the regulation (i.e., prior to the expenditure of funds and within 60 days of identifying an FCOI during the period of an award).

c) Alternatively, if the subrecipient does not have a compliant policy, include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures of SFIs. The subrecipient Investigator must disclose SFIs to the Company that are directly related to the subrecipient's work for the Company to enable the Company to identify, manage, and report identified FCOIs to NIH. The Company will monitor subrecipient Investigator compliance with any implemented management plan.

K. Public Accessibility Requirement

1. Company shall post this FCOI policy on the Company public website https://deltos.bio, as required by the NIH Grants Policy Statement Section 4.1.10 Financial Conflict of Interest at 4.1.10 Financial Conflict of Interest (nih.gov)

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2. FCOI Informational requests by the public concerning identified FCOIs held by senior/key personnel should be made to the President. The President shall respond to requests for FCOI information within five (5) business days for any SFI that meets all three of the following criteria:

- The SFI was disclosed, is still held by Senior/Key Personnel (the PD/PI and any other individual identified by Company as senior/key personnel in the application, progress report, or other NIH submission).
- Company has determined that the SFI is related to the NIH-funded research.
- Company has determined that the SFI constitutes an FCOI.

When the above conditions are met, Company will make available at least the following information available as provided for under applicable regulation 42 CFR 50.605(a)(5)(ii):

i. Investigator's name
ii. Investigator's title and role with respect to the research project
iii. Name of the entity in which the SFI is held
iv. Nature of the SFI
v. Approximate dollar value of the SFI in the following ranges: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000 and $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000; or a statement that the value cannot be readily determined by public prices or reasonable fair market value measures

The written response will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of the institution's identification of a new FCOI, which should be requested subsequently by the requestor.

L. Useful FCOI and NIH Resources

- NIH e-mail address for FCOI-related inquiries: fcoicompliance@mail.nih.gov
- FCOI Regulation 42 CFR Part 50 Subpart F - Promoting Objectivity in Research
- Financial Conflict of Interest
- FCOI Training
- Frequently Asked Questions (FAQs)
- NIH "Welcome Wagon" Letter: Information for New Recipient Organizations

M. Point of Contact

If you have a question related to the FCOI Policy of the Company, or would like to disclose a financial interest, contact us using the information below:

Contact:

Conor Loy
Deltos
innovation@deltos.bio