

Consegna Pharma Inc. Financial Conflict of Interest (FCOI) Policy

Effective August 2023

As an institution that applies for and/or receives Public Health Services (e.g., National Institutes of Health (NIH)) research funding via grants or cooperative agreements, Consegna Pharma Inc. (Consegna) is required to ensure that funded research is conducted without bias and with the highest ethical standards. To these ends, Consegna is establishing this Financial Conflict of Interest Policy (FCOI), in accordance with 42 CFR Part 50.

1. Scope and Responsibility

All Consegna investigators, personnel, and collaborators must comply with this policy. This policy may be amended or updated, as required or deemed necessary.

The Research Integrity Officer will be responsible for the solicitation and evaluation of any SFIs (Significant Financial Interests) and FCOIs, FCOI reporting, and the development and implementation of any management plans. The Research Integrity Officer may delegate this responsibility. This responsibility may also be designated to an alternative responsible official in the event that the Research Integrity Officer has an SFI that requires evaluation.

2. Definitions

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.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of Consegna, which may include, but are 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.

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

Significant Financial Interest (SFI):

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 Institutional Responsibilities:

- With regard to any publicly traded entity an SFI exists if the value of any remuneration received from the entity in the twelve (12) 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 the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value);
- With regard to any non-publicly traded entity, a SFI exists if the value of any remunerations from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or

dependent children) holds any equity interests (e.g. stock, stock options, or other ownership interest);

- Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
- 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 Institutional 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, medical center, or research institute that is affiliated with an Institution of higher education.

SFIs do not include the following types of financial interests:

- salaries, royalties or other remuneration paid by Consegna to the Investigator if the Investigator is currently employed or otherwise appointed by Consegna, including intellectual property rights assigned to Consegna and agreements to share in royalties related to such rights;
- any ownership interest in Consegna held by the Investigator;
- 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, 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.

Financial Conflict of Interest (FCOI): An SFI (defined above) that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

PHS Awarding Component: Any sub-agency or other component of the PHS, including NIH.

Research: Any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This includes basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Research under this policy does not include Phase I Small Business Innovation Research (SBIR).

3. Disclosures, Reviews, and Reporting

3.1 Investigator Disclosure

New Funded Research/New Investigators: All Investigators planning to participate in PHS-funded Research must disclose any SFIs (and those of the Investigator's spouse and dependent children) prior to the submission of an application for PHS-funded Research or prior to participating in any PHS-funded Research (to the extent an Investigator is added to the Research project after the initial application).

SFI Updates: Each Investigator participating in PHS-funded Research must submit an updated financial disclosure at least annually. Each annual disclosure must include any information that was not previously disclosed and any updated information regarding any previously disclosed SFI. Each Investigator must also submit an updated disclosure within thirty (30) days of discovering or acquiring a new SFI.

Form of Disclosure: Disclosures must be provided to The Research Integrity Officer and must be provided on the Consegna FCOI form, attached to this policy as Appendix 1. With respect to reimbursed or sponsored travel, disclosures shall include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. The Research Integrity Officer will determine whether further information on reimbursed or sponsored travel is needed. Such additional information may include the monetary value of the travel.

3.2 Financial Interest Review

Prior to expenditure of any PHS funds and beginning performance of a grant project; or, within sixty (60) days of an SFI disclosure, if during the course of PHS-funded research a new Investigator discloses a SFI, or an existing Investigator discloses a new SFI, the Research Integrity Officer will review the SFI to determine if it is related to PHS-funded research and, if so, whether the SFI constitutes a conflict of interest. An SFI will be deemed to be related to PHS-funded research when the Research Integrity Officer reasonably determines that the SFI: could be affected by the PHS-funded Research; or the relevant entity is one whose financial interest could be affected by the Research. An FCOI exists when Consegna, through the Research Integrity Officer, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research.

When reviewing an SFI, the Research Integrity Officer may involve the Investigator in the determination of whether an SFI is related to the PHS-funded research.

3.3 Reporting

All FCOIs must be reported to the PHS Awarding Component prior to the expenditure of any PHS funds and within sixty (60) days of any subsequently identified FCOIs. If an FCOI is eliminated prior to the expenditure of any PHS funds, FCOI reports are not required.

All FCOI reports must include the:

- Project number;
- Project Director/Principal Investigator ("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 FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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;
- A description of how the financial interest relates to the PHS-funded Research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- A description of the key elements of the Institution's management plan, including:
 - Role and principal duties of the conflicted Investigator in the Research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.

3.4 Retrospective Reviews

If an Investigator discloses or Consegna discovers a previously untimely, unreported, or unreviewed SFI, the Research Integrity Officer shall, within sixty (60) days review the SFI; determine whether it is related to PHS-funded research; and determine whether a FCOI exists.

If it is determined that there is an FCOI that was not timely identified, disclosed, or managed, or if an Investigator does not comply with a prior FCOI management plan, within one-hundred and twenty (120) days, the Research Integrity Officer shall conduct 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. The Research Integrity Officer shall document this review, which documentation shall include the:

- 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 FCOI;
- 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);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, Consegna shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Consegna shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, the above elements documented in the retrospective review, a description of the impact of the bias on the research project, and the Consegna's plan of action or actions 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).

3.5 Annual Reports

If Consegna has previously reported an FCOI to the PHS Awarding Component, on an annual basis and for the duration of the PHS-funded research project (including extensions with or without funds), Consegna shall provide the PHS Awarding Component with a report that addresses the status of the FCOI and any changes to the management plan. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. All such annual reports shall comply with any requirements communicated to Consegna by the PHS Awarding Component.

4. **Management of a FCOI**

In the event of an FCOI, the Research Integrity Officer shall, on a case by case basis, develop and implement a management plan specifying any actions that have been, and will be, taken to address the FCOI. Management plans shall aim to reduce or eliminate the FCOI to ensure (to the extent possible) that the design, conduct, and reporting of research will be free from bias. This may include, but is not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- 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;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

To the extent deemed necessary by the Research Integrity Officer, Consegna may also implement an interim management plan until the need for a full management plan can be determined or a full management plan can be developed.

If HHS determines that a PHS-funded clinical project, with the purpose of evaluating 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 Consegna, the involved Investigator must disclose the FCOI in each public presentation of the results of the research and request an addendum to any previously published presentations.

The Research Integrity Officer shall be responsible for monitoring the Investigator's compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

5. Public Disclosure

Within five (5) calendar days of a written request, Consegna will provide a written response to a request for information concerning any SFI that:

- was disclosed and is still held by the project director, principal Investigator, or any other Investigator;
- is related to the PHS-funded research; and
- is an FCOI.

The information that is made available will include:

- the Investigator's name;
- the Investigator's title and role with respect to the research project;
- the name of the entity in which the SFI is held;
- the nature of the SFI; and
- the approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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.

Information must remain available for disclosure for at least three years from the date that the information was most recently updated.

6. Records Management

Consegna shall maintain records of all Investigator financial interest disclosures, its review of the disclosed financial interest, its response to the disclosure, its determination of whether the disclosure results in an FCOI, and all actions taken under this policy or under a retrospective review. All records must be maintained for at least three (3) years from the date of the final expenditure report submitted to PHS, throughout the completion of any litigation, claim, negotiation, audit or other action involving the records, or other dates specified by law, governmental authority, or regulation, whichever is later. Consegna shall make all information relating to an Investigator financial interest disclosure, Consegna's review and response, and whether or not the disclosure resulted in a determination of an FCOI promptly available to HHS representatives.

7. Compliance, Enforcement Mechanisms, and Penalties for Non-Performance

In the event that an Investigator fails to comply with this FCOI policy or an FCOI management plan and such noncompliance appears to have biased the design, conduct, or reporting of the PHS-funded research, Consegna will promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

Failure to comply with this policy may result in consequences, including and up to removal from the Research or termination.

8. Subawards for PHS Research Effort

Subawards for research funded by a PHS Institution will be documented via a written agreement. This written agreement will specify whether this FCOI policy or the subrecipient's FCOI policy will apply to the relationship.

- To the extent that the subrecipient's FCOI policy will apply, the subrecipient must certify in its agreement with Consegna that its FCOI policy complies with 42 C.F.R. Part 50, Subpart F. The agreement must also specify that the subrecipient will be responsible for identifying all SFIs and determining whether an SFI constitutes an FCOI. The agreement must further specify that the subrecipient will be responsible for developing and monitoring a management plan, to the extent applicable. At Consegna's discretion, Consegna may participate in the determination of whether an SFI constitutes an FCOI and in the development of a management plan. Consegna will be responsible for submitting any required reports to NIH.
- To the extent that Consegna's FCOI policy will apply, the agreement will specify the timeframe within which the subrecipient must report to Consegna all SFIs. Consegna will be responsible for analyzing the SFI to determine whether it is an FCOI, for developing a management plan, and reporting to NIH. Consegna may request the assistance of the subrecipient with the foregoing analysis and management plan development and monitoring.

9. Public Accessibility

This policy will be available via Consegna's publicly accessible website.

10. Training Requirement

All Investigators must receive a copy of this or the applicable FCOI policy and must complete FCOI training, which training shall include the contents of this policy, the Investigator's responsibilities regarding disclosure of SFIs, and the applicable PHS regulations. Such training must be completed and documented prior to an Investigator engaging in PHS-funded research. Training will also be required (i) upon the effective date of this Policy, (ii) for each new Investigator, (iii) when this policy is updated (to the extent required to train the Investigators on the new material implemented), (iv) whenever an Investigator has been found not to be following this policy or a FCOI management plan, and (v) no less than every four years or as designated based on grant or role circumstances.

11. Point of Contact

Questions regarding this policy can be directed to Research Integrity Official at RIO@consegnapharma.com.

Appendix 1