Policy **10.0**
(Rev. Jun. 2023)

Respana Therapeutics, Inc.

Financial Conflicts of Interest

Purpose

This policy and related procedures have been developed to identify, manage, mitigate, neutralize, or eliminate actual, apparent, and potential financial conflicts of interest. The policy was written to be in conformance with the Code of Federal Regulations (CFR) 42, Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought* [1] and 45 CFR Part 94, *Responsible Prospective Contractors*.

[1] These regulations do not cover Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase I applications or awards but do apply to applicants and recipients under the SBIR/STTR Program Phase II. SBIR is the extramural research program for small business that was established by the Awarding Components of PHS and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. The term *SBIR Program* includes the STTR Program, which was established by Pub. L. 102-564.

Policy

As a pharmaceutical/biotechnology research and development corporation, Respana Therapeutics in compliance with federal regulations maintains a policy for on Financial Conflict of Interest in Research. Respana Therapeutics is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest.

Respana Therapeutics has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest.

The procedures described in this policy were created and designed primarily to comply with the specific regulatory requirements for U.S. Public Health Service (PHS)-sponsored research but are also intended to provide a basic framework and standards for identifying, evaluating, and managing potential financial conflicts of interest relating to Respana Therapeutics' other research activities. For non-PHS research, the specific steps, timing, determinations, documentation, and notifications may be tailored as appropriate but will remain focused on maintaining Respana Therapeutics' high standards for research integrity and effectively eliminating or managing actual or potential financial conflicts of interest.

Procedure **10.0**
(Rev. Jun. 2023)

Respana Therapeutics, Inc.

Internal Controls and Segregation of Duties

Definitions

For purposes of this policy, the following definitions shall apply:

Designated Official is the individual designated by Respana Therapeutics to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests.

Equity interest includes any stock, stock option, or other ownership interest, and its value may be determined through reference to public prices or other reasonable measures of fair market value.

Financial conflict of interest means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research as determined by Respana Therapeutics through the Designated Official.

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

Immediate family refers to an Investigator's spouse, domestic partner and dependent children.

Investigator means the project director/principal investigator and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of the research or proposed research.

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

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

PHS-funded Research means research funded under PHS grants, cooperative agreements, or contracts.

Public Health Service Act, or PHS Act means the statute codified at 42 U.S.C. 201 *et seq*.

Remuneration includes, for example, salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Research means 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 PHS-Funded Research, the term includes any such activity for which research funding is

available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.

Significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator and his/her immediate family that reasonably appear to be related to the Investigator's Respana Therapeutics project responsibilities, including:

1. With regard to interests in any **publicly traded entity,** a significant financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure and any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure, in which the value when aggregated exceeds $5,000;

2. With regard to interests in any **non-publicly traded entity,** a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure, in which the value when aggregated exceeds $5,000, or when the Investigator or his/her immediate family 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 related to such rights and interests.

Significant financial interests also include 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 the Investigator's Respana Therapeutics project 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; a medical center; or a research institute that is affiliated with an institution of higher education. The details of such disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Designated Official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.

Significant financial interest **does not include** the following:
Salary, royalties, or other remuneration paid by Respana Therapeutics (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by Respana Therapeutics, including that paid for intellectual property rights assigned to Respana Therapeutics and agreements to share in royalties related to such rights;

- Any ownership interest in Respana Therapeutics (or a subrecipient as applicable) held by the Investigator (e.g., Founder Stock, Stock Option Plan, Employee Stock Ownership Plan);
- 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.

Procedures

Responsibilities of Designated Official:

The Designated Official or his/her designee shall be responsible for the following:

- Informing Respana Therapeutics Investigators of their obligations under this policy and any related regulations;
- Reviewing disclosures of significant financial interest with Respana Therapeutics' CEO/Director, to determine whether they are related to the subject research and, if so, whether they constitute financial conflicts of interest;
- Screening and managing potential financial conflicts of interest;
- Maintaining all records relating to disclosures of financial interests, Respana Therapeutics' review of and response to such disclosures, and any related actions under this policy;
- Ensuring inclusion of any required certifications in applications for funding or contract proposals; and
- Reporting and disclosure as required under this policy and applicable regulations.

For PHS-funded research, the Designated Official shall also have the following responsibility:

- Taking reasonable steps to ensure that Investigators for subrecipients (e.g., subgrantees, subcontractors, or collaborators) fully comply with this policy or provide Respana Therapeutics with sufficient assurances to enable Respana Therapeutics' compliance with all applicable laws or regulations. To this end, the written agreement between Respana Therapeutics and the subrecipient will specify whether Respana Therapeutics' or the subrecipient's financial conflicts of interest policy will apply to the subrecipient's Investigators and, if the subrecipient's policy will apply, the Designated Official will:
  - Obtain certification from the subrecipient that its policy complies

with Respana Therapeutics' policy and the applicable regulations (absent such certification, Respana Therapeutics' policy will apply to the subrecipient's Investigators) and

- Establish time periods for subrecipient reporting of financial conflicts of interest to Respana Therapeutics that enable Respana Therapeutics to report such conflicts in a timely manner, as required under its policy and the applicable regulations.

If Respana Therapeutics' policy will apply to the subrecipient Investigators, Respana Therapeutics will be responsible for meeting the requirements of this policy and the reporting obligations reflected in the applicable regulations.

Responsibilities of Investigators and Internal Reporting Requirements:

For PHS-funded research in particular, as part of the funding application or proposal and prior to performing any work on the research, each Investigator who is planning to participate in the research is required by regulation to complete a Significant Financial Interest Disclosure (SFID) Form and submit the SFID Form to Respana Therapeutics' CEO/ Director. A template SFID Form is attached in Appendix 1 of this Policy. This requirement also applies to Investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS-funded research. SFID Forms will be provided to Investigators in conjunction with the training and will be otherwise made available.

Respana Therapeutics' CEO/Director, will review SFID submissions with the Designated Official. The information reported on the SFID Form includes a listing of the Investigator's known significant financial interests and those of his/her immediate family that reasonably appear to be related to the research or that are in entities whose financial interests could be affected by the research.

Respana Therapeutics Investigators in **non-PHS-funded research** who have any significant financial interest that may reasonably appear to be affected by the research are also expected to complete the SFID Form and submit it to Respana Therapeutics' CEO/Director, as part of the funding application or proposal and prior to performing any work on the research.

Investigators are expected to complete a separate SFID form for each research project and submit an updated SFID Form during the period of the award as necessary (at least annually for PHS- funded research). Such disclosures shall include any information that was not previously disclosed; any change in information regarding any previously disclosed significant financial interest; or, within 30 days of discovery or acquisition, any new significant financial interest (e.g., an interest acquired through purchase, marriage, or inheritance).

Determination and Management of Financial Conflicts of Interest:

Upon receipt of a completed SFID Form, the Designated Official shall determine whether an Investigator's significant financial interest is related to the subject research and, if so, whether the interest constitutes a financial conflict of interest under this policy and any applicable regulations. The Investigator may be required to submit additional information as part of the process. A disclosed interest may be related to the

subject research either because the interest

could be affected by the research or because it is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.
If Respana Therapeutics determines that a financial conflict of interest exists, a financial conflicts of interest management plan will be implemented and monitored on an ongoing basis. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing the research);
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest; or
- Severance of relationships that create actual or potential conflicts.

In addition to the conditions or restrictions described above, Respana Therapeutics may require the management of conflicting financial interests in other ways as it deems appropriate.

External Reporting Requirements:

Respana Therapeutics will disclose financial conflicts of interest as required by applicable laws or regulations. Before expending any funds under a PHS award, Respana Therapeutics will ensure public accessibility by posting financial conflicts of interest information on a publicly available web site or by responding in a timely manner to written requests as required under the regulations. The Designated Official will also report to the PHS Awarding Component, as detailed in the regulations, the existence of any financial conflict of interest that has not been eliminated and will ensure that Respana Therapeutics has implemented a plan to manage the conflict.

If a financial conflict of interest is identified after its initial reporting and during ongoing research (e.g., through participation of a new Investigator) and has not been eliminated, Respana Therapeutics will provide the PHS Awarding Component with an update within 60 days and ensure that it has implemented a plan to manage the conflict. If the financial conflicts of interest report involves a significant financial interest that was not disclosed by an Investigator or not previously reviewed or managed by Respana Therapeutics (e.g., not reviewed or reported by a subrecipient in a timely manner), Respana Therapeutics will undertake a retrospective review. Such retrospective review will determine whether there was bias in the design, conduct, or reporting of the PHS-funded research, or portion thereof, conducted prior to the identification and management of the conflict. If bias is found, Respana Therapeutics will promptly notify the PHS Awarding Component and submit a mitigation report. Upon request, Respana Therapeutics will provide HHS with information
relating to any Investigator disclosure of significant financial interests; Respana Therapeutics' review of,

and response to, such disclosure; and whether the disclosure resulted in Respana Therapeutics' determination of a financial conflict of interest.

Confidentiality:

Respana Therapeutics will, to the extent possible, protect the confidentiality of disclosures. In every instance, Respana Therapeutics will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to Respana Therapeutics staff only on a need-to-know basis and will not be disclosed outside of Respana Therapeutics unless necessary to comply with contractual, legal, or regulatory requirements.

Investigator Noncompliance:

If an Investigator knowingly fails to comply with this policy, Respana Therapeutics may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. In addition, for PHS-funded research, failure to comply with this policy or the applicable regulations shall result in the following:

- If the Investigator's failure to comply with this policy or a financial conflicts of interest management plan has biased the design, conduct, or reporting of the PHS-funded research, Respana Therapeutics shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;
- Respana Therapeutics will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts; and

If HHS determines that a clinical PHS-funded research project 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 financial conflict of interest that was neither disclosed nor managed, Respana Therapeutics shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

Training and Education:

Investigators receive continuing education on human subject protections in research as well as trainings to promote objectivity in research and to ensure Investigator compliance with regard to the applicable regulations and significant financial interest disclosure obligations.

- Respana Therapeutics requires Investigators to complete such training at least every four years, and when any of the following occurs:
- Respana Therapeutics revises its financial conflicts of interest policy or procedures in any manner that affects the Investigator's obligations;
- An Investigator is new to Respana Therapeutics; or
- Respana Therapeutics finds that an Investigator is not in compliance with this policy or a financial conflicts of interest management plan.

As part of the FCOI training, investigators should complete the NIH FCOI Tutorial that can be found at: https://grants.nih.gov/grants/policy/coi/fcoi-training.htm

Retention of Records:

The Designated Official will retain financial conflicts of interest disclosure forms and other supporting information consistent with Respana Therapeutics' Record Retention policy. For PHS-funded research, records of all financial disclosures, whether or not they result in a reporting obligation, and all actions taken by Respana Therapeutics with respect to each financial conflict of interest will be retained for at least 3 years from the date of submission of the final expenditures report or final payment on the contract or, where applicable, from other dates specified in 45 C.F.R. 75.361.

Supersession (Replacement)/Cancellation

N/A

Maintenance

This policy becomes effective on the date that the Chief Executive Officer (CEO) signs it and remains in effect until officially suspended or cancelled by the CEO.

DocuSigned by:
74105EA678284DE...

President & CEO

Signature, Title

6/15/2023

Date

Appendix **1.0**
(Rev. Jun. 2023)

Respana Therapeutics, Inc.

Conflict of Interest
Significant Financial Interest Disclosure (SFID) Form
Part I

All Respana Therapeutics Laboratories investigators seeking U.S. Public Health Service (PHS)-sponsored research or non-PHS sponsored external funding to conduct research activities are required to complete and file a signed Significant Financial Interest Disclosure (SFID) Form and submit the SFID Form to Respana Therapeutics' CEO/Director. Each investigator must complete this form before a funding proposal/application is submitted.

Specific Instructions: Place a check in the appropriate column for each question. Once every question is answered, the investigator must certify the information by signing the bottom of the form and forwarding this Form to Respana Therapeutics CEO.

Investigator Name: _____

Department/Project Team (if applicable):

Question	**Yes**	**No**
Do you, your **spouse** or dependent child(ren) hold a position of management, such as board member, director, officer, partner, trustee, employee or consultant with a sponsor, a vendor or (sub) contractor related to the proposed or current PHS-funded research/sponsored program activity?	☐	☐
Do you, your spouse or dependent child(ren) have Significant Financial Interest (See Definitions) in a Sponsor, a vendor or (sub) contractor related to your proposed or current PHS-funded research/sponsored program activity?	☐	☐
Is it reasonable to anticipate that your financial interest could be directly and significantly affected by the design, conduct, or reporting of your proposed or current PHS-funded research/sponsored program activity?	☐	☐

If you answered "*No*" to ALL of the questions above, your Disclosure is complete; you do not have to submit Part II. Please sign and date the certification below.

If you answered "***Yes*" to ANY question above,** please complete a separate Part II for **every** outside organization with which you have the relationship(s) indicated above.

Investigator Certification:

- I have read and understood the Policy on Financial Conflict of Interest.
- I agree to file a new or updated Disclosure of Significant Financial Interests and Obligations form if the answer to any of the above questions changes.
- I certify that the answers to the declaration are accurate and truthful to the best of my knowledge.

Signature:_____ Date: _____

Conflict of Interest Form
Significant Financial Interest Disclosure (SFID) Form
Part II

Complete Part II only if you answered, "YES" to at least one of the questions in Part I.

Attach one Part II form for each organization with which you have the relationship(s) indicated in Part I.

Investigator Name:

Number of Part II forms submitted: , of which, this is number:

1. Name of organization:

2. Financial relationship(s) with the organization (check all that apply):
   - ☐ Consultant
   - ☐ Employee
   - ☐ Equity Interest
   - ☐ Recipient of
   - ☐ Honoraria Recipient of Royalties
   - ☐ Other (Describe):

3. The financial relationship is between the organization and (check all that apply):
   - ☐ Self
   - ☐ Spouse
   - ☐ Dependent Child(ren)

4. If the organization is a publicly traded entity, have you, your spouse, or dependent children obtained in the last 12 months or do you anticipate obtaining in the next 12 months remuneration or equity from the entity in the previous twelve months that, 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.
   Y ☐ N ☐ N/A ☐

5. If the organization is a non-publicly traded entity, have you, your spouse, or dependent children obtained in the last 12 months or do you anticipate obtaining in the next 12 months remuneration that, when aggregated, exceeds $5,000, or do you hold any equity interest (e.g., stock, stock option, or other ownership interest)?
   Y ☐ N ☐

6. Do you, your spouse, or dependent children hold intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to relationship with the organization?
   Y ☐ N ☐

7. What relationship, if any, is there between the business or activities of the organization and your current or planned areas of research?