RIDGELINE THERAPEUTICS
PHS-FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

Persons covered by this Policy

This policy applies to all employees, including all full-time, part-time, temporary, and contract employees, of Ridgeline Therapeutics ("RLT") who are planning to participate in, or are participating in, Public Health Service ("PHS")-funded research by means of a grant or cooperative agreement.

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 Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest and to prevent an employee's activities from adversely influencing RLT's operations.

2. It is recognized that research related conflicts of interest can arise from legitimate and appropriate activities including economic development, public-private interactions, and employee's and their family's personal business relationships.

3. 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" and 45 CFR Part 94 "Responsible Prospective Contractors" as well as all other relevant policies of federal funding and oversight agencies.

4. Financial conflicts of interest (FCOI) in research may occur when outside financial interests compromise, or have the appearance of compromising, the professional judgment of an Investigator when designing, conducting, or reporting research.

Disclosing FCOI

All Ridgeline Investigators (names on proposal budgets: Principal Investigators [PIs], scientists, consultants etc.) must disclose whether or not they have Significant Financial Interest (SFI) for every funding proposal using the Financial Conflict of Interest Disclosure (Disclosure) form. Each person is required to file their own separate disclosure form. The disclosure and reporting obligation also applies to Investigators who are working on a subaward. This disclosure should occur prior to engaging in research related to any PHS-funded grant or contract (except Phase I SBIR/STTR applicants and/or recipients. Fast Track SBIR/STTRs recipients are subject to the FCOI regulation prior to NIH's award of the type 4 R44, U44, R42, and UT2 Phase II SBIR/STTR awards.)

A. Statement of general policy

1. The design, conduct, and reporting of Research funded under Public Health Service

(PHS) 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 perceived and real conflicts of interest annually (each December of the current calendar year) and provide new or updated disclosures in a timely manner; RLT shall provide for the elimination or management of Financial Conflicts of Interest; and RLT shall make disclosures to both the PHS 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.

4. For matters subject to this policy, to the extent of any conflict between this policy and provisions of the general RLT Conflict of Interest Policy, this policy shall control.

5. Nothing in this policy shall be construed to limit or abridge the authority of RLT management to take such action as they deem appropriate regardless of any action or inaction by an employee of RLT.

B Definitions

Company refers to Ridgeline Therapeutics (RLT).

Investigator means the project director or principal Investigator (PD/PI) 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, research scientists, collaborators, or consultants.

Company responsibilities means an Investigator's professional responsibilities on behalf of the Company (Ridgeline Therapeutics), and as defined by the Company, including, but not limited to, activities such as research, research consultation, teaching, professional practice, Company committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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

Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

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.

Senior/Key Personnel means the Project Director/Principal Investigator (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 NIH by the Company under the regulation.

Significant Financial Interest (SFI) is defined by the regulation as:

1. 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, 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

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

2. 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 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 Company's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Company's FCOI policy, the Company official(s) 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.

3. The term *Significant Financial Interest* does not include the following types of financial interests: 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; any ownership interest in the Company held by the Investigator, if the Company is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

C. Policy Implementation

1. Training Required:

Investigators shall complete FCOI training provided by the Company on or before their becoming subject to this policy and then every four (4) years thereafter. Currently, RLT uses the NIH web-based training which can be accessed at: (http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm). Investigators must save and print the FCOI Certificate as proof of completion. 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.

2. Disclosure Requirement:

(i) An Investigator shall disclose any situation in which the Investigator has, or may have, a real or potential Significant Financial Interest as defined and provided for herein. Research should not be undertaken where a Significant Financial Interest is present until a determination and approval has been made pursuant to this policy.

(ii) RLT has adopted an electronic form, Investigator FCOI Disclosure Form, which fulfills the FCOI disclosure of SFIs. This form is included in the Employee Handbook. The Disclosure must identify Significant Financial Interests of the Investigator, spouses/registered domestic partners, and dependent children that exceed the thresholds set by PHS and that relate to any of the "Investigator's" Company responsibilities.

(iii) Each Investigator named on a PHS-funded proposal (other than a Phase 1 SBIR/STTR proposal) must complete and submit a copy of the Disclosure to the PI/PD of the PHS proposal for which a SFI exists, whether RLT is the Lead or a subrecipient. It is important to note that a new Disclosure must be completed for each new proposal opportunity. Once the Disclosure is completed, the Investigator sends it and the training certificate (discussed below) to the PI/PD, who then compiles the forms from each individual and forwards this information to the Company's Grant Signing Official (SO) for review and oversight. Review of Disclosures by the SO shall occur within sixty (60) days of receipt by PI/PD.

(iv) Investigators shall keep their supervisors, and the PI/PD of any PHS grant or contract for which a SFI exists, informed of the Investigator's SFI. If a supervisor or PI/PD becomes aware of a conflict of 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 RLT to anticipate the receipt of a new Disclosure.

3. Disclosure Frequency:

(i) Disclosure must be made annually to RLT, during month of December of the current calendar year. If no Significant Financial Interest is present a Disclosure must still be submitted that states “none”. The date such an annual Disclosure is due during December of the current calendar year and no later than December 30 of the current calendar year.

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

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

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

4. Review and Management:

(i) The Company shall authorize either the Grants Signing Official (SO) or a committee of appropriate composition and skills to review the Disclosure and determine if it is a FCOI. This committee shall be known as the Research Conflict of Interest Committee ("Committee") and serve at the pleasure of the Company.

(ii) If a determination is made that a FCOI exists the SO or Committee shall seek input from the Investigator and recommend to the Company a suitable action plan (“Management Plan”) to eliminate or manage the FCOI consistent with the objectives of this policy. The Management Plan shall provide for its periodic review and updating at least annually (i.e., during December of the current calendar year). 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.

(iii) Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are 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 financial conflict of interest;

- 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.

(iv) The Company management shall review the proposed Management Plan and can approve, modify and approve, or return to the Committee for additional work. Final review and determination must be completed prior to the expenditure of any PHS funds for the applicable Research.

(v) The SO and PI/PD will retain all FCOI-related records relating to all Investigator disclosures of financial interests and the Company's review of, and response, to such disclosures (whether or not a Disclosure resulted in the Company's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three (3) years from the date the final expenditures report is submitted to the PHS (NIH).

D. Violations and Sanctions

1. Sanctions: Violations of Company policies, including the failure to avoid a prohibited activity or disclose a conflict of 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. Retrospective Review:

(i) The Company shall complete retrospective reviews of determinations of noncompliance with this policy within 120 days of the determination.

(ii) The retrospective reviews shall be documented; such documentation shall include, but not necessarily be limited to, all of the following key elements: 1. Project number; 2. Project title; 3. PD/PI or contact PD/PI if a multiple PD/PI model is used; 4. Name of the Investigator with the FCOI; 5. Name of the entity with which the Investigator has a financial conflict of interest; 6. Reason(s) for the retrospective review; 7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); 8. Findings of the review; and 9. Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, the Company shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

(iv) If bias is found, the Company is required to 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 (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). Thereafter, the Company will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, the Company may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS- funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Company's retrospective review.

3. 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 a FCOI that was not managed or reported by the Company as required by this policy, RLT 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.

E. Company Reporting

1. The Company shall provide annual (during December of the current calendar year) and revised reports of FCOI to PHS/National Institutes of Health (NIH) per the applicable regulations.

2. The Company shall notify PHS/NIH of bias found in the design, conduct, or reporting of PHS/NIH funded Research including whether Investigator failure to comply with this FCOI policy or management plan appears to have caused such bias.

3. FCOI records shall be maintained for at least three (3) years from the submission of the final expenditure reports for the pertinent PHS/NIH funding or longer as required by other policy or regulation.

4. FCOI Informational requests by the public should be made to the Company. The Company shall respond to requests for FCOI information within five (5) business days as provided for under applicable regulations.

F. Subrecipients

Company shall require subrecipient compliance with pertinent FCOI requirements as mandated by PHS regulation.