COLLABORATION AGREEMENT

This Agreement is made by and between the National Cancer Institute , an agency of the United States Government, (hereinafter referred to as "**NCI"**), and _____(hereinafter referred to as "Entity"). Collectively or individually, the **NCI** and Entity shall also be referred to as "Parties" or "Party."

Each Party is interested in collaborating on a joint project described by the Research Plan attached as Appendix A, and the Parties agree as follows:

1. Each Party may transfer Research Material to the other Party as described in the Research Plan. Each Party retains title to its Research Material.

2. To the extent both Parties decide to transfer material not already described in the Research Plan, each such transfer must be documented in writing and notice must be copied to each Party prior to the transfer of the additional material and such material will be treated as Research Material under this Agreement. The Parties will not transfer Human Material under this Agreement. "Human Material" means material that is directly obtained from human subjects (including genomic DNA and isolated RNA) and derivatives of material originally obtained from human subjects that are identified or coded (including infectious agents). Entity acknowledges that Research Material provided by NCI may be subject to the NCI Letter of Collection with the Source Country of the Research Material. For purposes of clarity, "Source Country" will refer to the country which has provided the raw natural product from which the specific chemical substance under investigation was derived.

3. THE RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. Recipient agrees to comply with all U.S. Federal rules and regulations applicable to the research project and the handling of the Research Material.

4. A Party that receives Research Material ("Recipient") from the other Party ("Provider") agrees to retain control over the Research Material and will not transfer the Research Material to third parties, except Recipient's contractors or agents, without advance written approval of the Provider. Research Material will only be used to conduct the research outlined in the Research Plan by Recipient's investigator, contractors, or agents who have a need to use the Research Material in connection with the Research Plan and whose obligations of use are consistent with, but no less stringent than, the terms of this Agreement. Recipient will not use Provider's Research Material in a for-profit manner such as for production or for sales of the Research Material. When the research is completed or within thirty (30) days of termination of this Agreement, whichever occurs first, Recipient will dispose of the Provider's Research Material as directed by Provider.

5. For the purposes of this Agreement, “Confidential Information” includes any information relating to the Research Plan that a Party transfers to a receiving Party and asserts is confidential and proprietary. Confidential Information shall not include information that:

a. is generated by either Party under the Research Plan (“Research Results”), which, for clarity, shall be maintained in confidence unless disclosed in accordance with Paragraph 9;
b. has been published or otherwise publicly available at the time of disclosure to the receiving Party;
c. becomes publicly known, by publication or otherwise, not due to any unauthorized act by the receiving Party;
d. was in the possession of or was readily available to the receiving Party without being subject to a confidentiality obligation from another source prior to the disclosure;
e. the receiving Party can demonstrate it developed independently, or it acquired without reference to or reliance upon such Confidential Information; or
f. is required to be disclosed by law, regulation or court order.

6. All information to be deemed confidential under this Agreement shall be clearly marked "**CONFIDENTIAL**" by the disclosing Party. Any Confidential Information that is orally disclosed must be reduced to writing and marked "**CONFIDENTIAL**" by the disclosing Party, and such notice must be provided to the receiving Party within thirty (30) days of the oral disclosure.

7. Each Party agrees to accept the Confidential Information and employ all reasonable efforts to maintain the Confidential Information of the other Party confidential, such efforts to be no less than the degree of care employed by each Party to preserve and safeguard its own confidential information. The Confidential Information of the disclosing Party shall not be disclosed, revealed, or given to anyone by the receiving Party, except employees, contractors, or agents of the receiving Party who have a need for the Confidential Information in connection with the receiving Party's activities under this Agreement, and who are under confidentiality obligations to the receiving Party that are consistent with, but no less stringent than, this Agreement. Such employees, contractors, and agents shall be advised by the receiving Party of the confidential nature of the Confidential Information and that the Confidential Information shall be treated accordingly. The obligations of this Paragraph 7 shall continue for five (5) years from the execution of this Agreement.

8. “Modifications” means substances created under the Research Plan by one Party which contain/incorporate Research Material of the other Party. The Parties agree to share Modifications with each other as available and upon request. Either Party can use Modifications for their own internal research purposes. Either Party may make Modifications available to non-profit entities for research purposes only. A Party that

wishes to distribute Modifications to for-profit entities for any purpose or to any third party for commercial purposes agrees that it will not do so unless it has first notified the other Party.

9. The Parties agree to exchange all Research Results. Research Results will be jointly-owned by the Parties, and may be freely used by each Party for activities outside the scope of the Research Plan. The Parties agree to work together to make Research Results publicly available and will use reasonable efforts to keep the Research Results confidential until published or until a corresponding patent application has been filed, whichever occurs first. Before either Party submits a paper or abstract for publication, the other Party shall have thirty (30) days to review the proposed publication to ensure that Confidential Information or any intellectual property therein is protected. The reviewing Party may request in writing that the proposed publication be delayed for up to thirty (30) additional days as necessary to file a patent application. Each Party will be given seven (7) days to review and provide comments on any press releases relating to this Agreement. Each Party agrees not to claim, infer, or imply endorsement of itself, its research, or any of its products or services, by the other Party or any of its employees or subunits.

10. **Source Country Obligations.** As an agency of the United States Government, NCI complies with the United States Government's policy to follow the principles articulated in the United Nations Convention on Biological Diversity ("U.N. CBD"). The U.N. CBD calls for "sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Source Country providing such resources" (U.N. CBD Article 15.7). The "Source Country" will refer to the country which has provided the raw natural product from which the specific chemical substance under investigation or a derivative thereof was derived. A "Source Country Organization" will refer to an organization which has provided, on behalf of a Source Country, the raw natural product from which the specific chemical substance under investigation or a derivative thereof was derived.

In order to abide by these principles and address the interests of the Source Country, Recipient agrees that, should the Materials eventually be developed and the resulting product marketed by the Recipient, or licensed by Recipient to a company or other institution for development and commercialization (whether the product is a direct isolate from the Materials, structurally based upon an isolate from the Materials, a synthetic material for which the Materials provided a key development lead, or a method of synthesis or use of any aforementioned isolate, product, or material), the Recipient or Recipient's licensee(s) will negotiate and enter into an agreement with the appropriate Source Country or Source Country Organization. This agreement between the Recipient or Recipient's licensee(s) and Source Country or Source Country Organization must commence prior to the start of clinical development studies that are conducted, directed, or sponsored by either Recipient or Recipient's licensee(s). Negotiations must be

completed and an agreement executed prior to commercial sale of product resulting from the Research Project. This agreement relating to the product must be binding upon the Source Country, or their designee and Recipient, and any licensee(s) or assignees of Recipient, with respect to any intellectual property rights relating to the product.

Recipient will seek to utilize the Source Country as its first source of supply either for commercial sale of Materials or for cultivation of raw (natural product) materials required for the manufacture of a product (regardless of whether the product is an isolated natural product or is structurally based thereon) if such material can be made available in a timely manner in quantities and quality sufficient for use by the Recipient at a mutually agreeable fair price. If such material must be cultivated, Recipient agrees to seek to utilize the Source Country as its first source of such cultivation efforts.

11. This Agreement shall remain in force for three (3) years or until the research has been completed, whichever occurs first. The term may be extended and the provisions of this Agreement may be modified only by amendment signed by the duly authorized signatory for each Party. The Agreement may be terminated by either Party for any reason by providing written notice at least thirty (30) days prior to the desired termination date.

12. Each Party shall retain title to any intellectual property rights in inventions and works of authorship made by its employees in the course of the research. The Parties understand that nothing herein shall be deemed to constitute, by implication or otherwise, the grant to either Party by the other of any license or other rights under any patent, patent application, or other intellectual property right or interest. NIH will seriously consider Entity's request for a license to any invention made in whole or in part by NCI under the research described in the attached Research Plan, subject to the terms of 35 U.S.C. Section 207-209 and 37 C.F.R. Part 404.

13. THE PROVIDER OFFERS NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. The Party providing Research Material or Confidential Information makes no representations that the use thereof will not infringe any patent or proprietary rights of third parties. No indemnification for any loss, claim, or liability is intended or provided by either Party under this Agreement.

14. This Agreement constitutes the entire understanding between the Parties concerning the subject matter of this collaboration and supersedes any prior understanding or written or oral agreement. The illegality or invalidity of any provision of this Agreement shall not impair, affect or invalidate the other provisions of this Agreement. The relationship of the Parties is that of independent contractors and not agents of each other or joint venturers or partners. Each Party shall maintain sole and exclusive control over its personnel and operations.

14. Each Party expressly certifies and affirms that the contents of any statements made herein are truthful and accurate to the best of its knowledge and belief, and each official signing this Agreement on behalf of a Party further certifies and affirms that the official has the authority to do so.

15. Articles 5-15 survive termination or expiration of this Agreement. For clarity, the obligations to the Source Country in Article 10 survive in perpetuity.

SIGNATURES APPEAR ON THE FOLLOWING PAGE

ACCEPTED AND AGREED

FOR THE NATIONAL CANCER INSTITUTE

_____ _____

(Authorized Signatory for NCI) Date
Jeffrey W. Thomas, Ph.D.
Unit Supervisor, TTC, NCI

NCI Technology Transfer Center
8490 Progress Drive, Suite 400
Frederick, MD 21701

READ AND UNDERSTOOD:

_____ _____

(NCI Investigator Name) Date
Barry O'Keefe, Ph.D.

FOR THE ENTITY

_____ _____

(Authorized Signatory for Entity) Date
(Printed Name)
(Title of Signatory)

Address for Notices:

READ AND UNDERSTOOD:

_____ _____

(Entity Investigator Name) Date

APPENDIX A

Research Plan

[Title]

NCI Investigator:
Mailing Address:
Telephone #:

Entity Investigator:
Mailing Address:
Telephone #:

I. Research Material and Confidential Information to be exchanged between the Parties

For the NCI:

Research Material provided by the NCI:

Confidential Information provided by the NCI:

For the Entity:

Research Material provided by the Entity:

Confidential Information provided by the Entity:

II. Project Description

III. Goals:

IV. Activities of the Parties

NCI**:**

Entity:

Both Parties jointly: