NATIONAL INSTITUTES OF HEALTH

NON-EXCLUSIVE PATENT LICENSE AGREEMENT
FOR INTERNAL COMMERCIAL USE

This **Agreement** is entered into between the National Institutes of Health ("**NIH**") or the Centers for Disease Control ("**CDC**"), hereinafter singly or collectively referred to as "**PHS**," agencies of the United States Public Health Service within the Department of Health and Human Services ("**DHHS**") through the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 U.S.A.; and _____ ("**Licensee**"), having an office at _____.

PHS and **Licensee** agree as follows:

1. BACKGROUND

1.01 In the course of conducting biomedical and behavioral research, **PHS** investigators made inventions that may have commercial applicability.

1.02 By assignment of rights from **PHS** employees and other inventors, **DHHS**, on behalf of the United States Government, owns intellectual property rights claimed in any United States and foreign patent applications or patents corresponding to the assigned inventions. **DHHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.

1.03 The Assistant Secretary for Health of **DHHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology Transfer Act of 1986, 15 U.S.C. §3710a, and the regulations governing the licensing of Government-owned inventions, 37 CFR Part 404.

1.04 **PHS** desires to transfer these inventions to the private sector through commercial research licenses to facilitate the commercial development of products and processes for public use and benefit.

1.05 **Licensee** desires to acquire the rights to use certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.01 "**Licensed Patent Rights**" shall mean:

a) U.S. patent applications and patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;

b) to the extent that the following contain one or more claims directed to the invention or inventions claimed in a) above: *i)* continuations-in-part of a) above; *ii)* all divisions and continuations of these continuations-in-part; *iii)* all patents issuing from such continuations-in-part, divisions, and continuations; and *iv)* any reissues, reexaminations, and extensions of all such patents;

c) to the extent that the following contain one or more claims directed to the invention or inventions claimed in a) above: all counterpart foreign applications and patents to a) and b) above, including those listed in Appendix A.

Licensed Patent Rights shall *not* include b) or c) above to the extent that they contain one or more claims directed to new matter which is not the subject matter of a claim in a) above.

2.02 "**Licensed Product(s)**" means tangible materials, identified in Appendix B, which, in the course of manufacture, use, or sale would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgement of a court of competent jurisdiction.

2.03 "**Licensed Process(es)**" means processes, identified in Appendix B, which, in the course of being practiced would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgement of a court of competent jurisdiction.

2.04 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.05 "**Government**" means the government of the United States of America.

2.06 "**Licensed Fields of Use**" means internal commercial use and/or product development.

3. GRANT OF RIGHTS

3.01 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a Nonexclusive License under the **Licensed Patent Rights** in the **Licensed Territory** to make and to use, but not to sell the **Licensed Products** and **Licensed Processes** in the **Licensed Fields of Use** only.

3.02 **Licensee** has no right to grant sublicenses.

3.03 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than **Licensed Patent Rights** regardless of whether such patents are dominant or subordinate to **Licensed Patent Rights**.

3.04 **PHS** acknowledges that information related to the **Licensed Patent Rights** may be of assistance to **Licensee** in its commercialization efforts. Accordingly, **PHS** will consider reasonable requests by **Licensee** for access to the inventors of the **Licensed Patent Rights**.

4. ROYALTIES

4.01 **Licensee** agrees to pay to **PHS** a non-creditable, nonrefundable license issue royalty as set forth in Appendix C within thirty (30) days from the date this **Agreement** becomes effective.

4.02 **Licensee** agrees to pay to **PHS** a nonrefundable annual royalty as set forth in Appendix C. The annual royalty is due and payable on the anniversary date of the effective date of this agreement of each calendar year. The first annual royalty is due and payable within thirty (30) days from the date this **Agreement** becomes effective.

4.03 All payments due under this **Agreement** shall be paid in U.S. dollars, net of all non-U.S. taxes, and shall be made by check or bank draft drawn on a United States bank and made payable to "NIH/Patent Licensing." All payments due under this **Agreement** shall be mailed to the following address: NIH, P.O. Box 360120, Pittsburgh, Pennsylvania 15251-6120. Interest and penalties may be assessed by **PHS** on any overdue payments in accordance with the Federal Debt Collection Act. The payment of such late charges shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

5. PERFORMANCE

5.01 **PHS** agrees, if **Licensed Products** are available to **PHS**, to provide **Licensee** with samples of the **Licensed Products** and, at reasonable cost to **Licensee**, to replace them in the event of their unintentional destruction. **Licensee** agrees to retain control over the **Licensed Products** and shall not distribute or release them to others without the prior written consent of **PHS**.

5.02 **Licensee** shall expend reasonable efforts and resources to carry out the research development plan submitted with **Licensee**'s application for a license and shall begin research within six (6) months of the effective date of this **Agreement**.

5.03 **Licensee** agrees in its use of any **PHS**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including Public Health Service and National Institutes of Health regulations and guidelines. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

5.04 **Licensee** shall provide written annual reports within sixty (60) days of the end of each calendar year detailing the current status of on-going research using **Licensed Products**.

5.05 All plans and reports required by this Article 5 shall be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential and, to the extent permitted under the research development plan by law, not subject to disclosure under the Freedom of Information Act, 5 U.S.C. §552.

6. NEGATION OF WARRANTIES AND INDEMNIFICATION

6.01 **PHS** offers no warranties other than those expressly specified in this **Agreement**.

6.02 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

6.03 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE of any subject matter defined by the claims of the **Licensed Patent Rights** or of any material provided to **Licensee** under Paragraph 5.01.

6.04 **PHS** does not represent that it will commence legal actions against third parties infringing the **Licensed Patent Rights**.

6.05 **Licensee** shall indemnify and hold **PHS** and its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of a) the use by **Licensee**, its directors, employees, or third parties of any **Licensed Patent Rights**, or b) the design, manufacture, distribution, or use of any **Licensed Products** or materials provided under Article 5.01, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**. **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

7. TERMINATION AND MODIFICATION OF RIGHTS

7.01 This **Agreement** is effective when signed by all parties and shall terminate at the time specified in Appendix B, unless previously terminated under the terms of Article 7 below.

7.02 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, **PHS** may terminate this **Agreement** by written notice.

7.03 **PHS** shall specifically have the right to terminate this **Agreement** by written notice if **Licensee**: 1) has not demonstrated that it is executing the research plan submitted with its application for a license or that it has taken or can be expected to take, within a reasonable time, effective steps to achieve the practical application of the **Licensed Patent Rights** as contemplated by this **Agreement**; or 2) has willfully made a false statement of or willfully omitted a material fact in its application for a license or in any report required by this **Agreement**.

7.04 **PHS** reserves the right according to 35 U.S.C. §209(f)(4) to terminate this **Agreement** if it is determined that such action is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license and such requirements are not reasonably satisfied by **Licensee**.

7.05 **Licensee** shall have a unilateral right to terminate this **Agreement** by giving **PHS** sixty (60) days' written notice to that effect.

7.06 Within thirty (30) days of receipt of written notice of **PHS**'s unilateral decision to terminate this **Agreement**, **Licensee** may, consistent with the provisions of 37 CFR §404.11, appeal the decision by written submission to the Director of NIH or designee. The decision of the NIH Director or designee shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

7.07 If either Party desires a modification to this **Agreement**, the Parties shall, upon reasonable notice of the proposed modification by the Party desiring the change, confer in good faith to determine the desirability of such modification. No modification will be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

7.08 Within thirty (30) days of the termination of this **Agreement** under this Article 7 or expiration under Paragraph 7.01, **Licensee** shall submit payment of any royalties due and shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to **PHS** or provide **PHS** with certification of their destruction.

7.09 Paragraphs 4.03, 5.05, 6.01, 6.02, 6.03, 6.04, 6.05, 7.06, and 7.08 of this **Agreement** shall survive termination of this **Agreement**.

8. GENERAL PROVISIONS

8.01 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

8.02 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

8.03 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

8.04 All notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail properly addressed to the other Party at the address designated on the following Signature Page, or to such other address as may be designated in writing by such other Party, and shall be effective as of the date of the postmark of such notice.

8.05 This **Agreement** shall not be assigned by **Licensee** except a) with the prior written consent of **PHS**; or b) as part of a sale or transfer of substantially the entire business of **Licensee** relating to operations which concern this **Agreement**.

8.06 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material and other commodities. The transfer of such items may require a license from the cognizant agency of the U.S. Government or written assurances by **Licensee** that it shall not export such items to certain foreign countries without prior approval of such agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.

8.07 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of the **Agreement**, except for appeals of modification or termination decisions provided for in Article 7. **Licensee** agrees first to appeal any such unsettled claims or controversies to the Director of NIH or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.

SIGNATURES BEGIN ON NEXT PAGE

PHS NON-EXCLUSIVE PATENT LICENSE AGREEMENT
FOR INTERNAL COMMERCIAL USE

FOR **PHS**:

by:_____ _____
Jack Spiegel, Ph.D. Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address for Notices:

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852

FOR **Licensee** (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):

_____
Licensee

by:_____ _____
Signature of Authorized Official Date

_____
Printed Name

_____
Title

Mailing Address for Notices: _____

_____

_____

_____

APPENDIX A – Patent(s) or Patent Application(s)

Patent(s) or Patent Application(s):

APPENDIX B – Licensed Product(s), Process(es), and Territory

Licensed Product(s):

Licensed Process(es):

Licensed Territory:

Termination:

This **Agreement** shall terminate _____ (___) years from the effective date as defined in Paragraph 7.01.

APPENDIX C § Royalties

Royalties:

Licensee agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty in the amount of_____.

Licensee agrees to pay to **PHS** a noncreditable, nonrefundable annual royalty in the amount of _____.

APPENDIX D S Modifications

PHS and **Licensee** agree to the following modifications to the Articles and Paragraphs of this **Agreement**: