For NIH’s internal use only:

License Number:

License Application Number:

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

Licensee:

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention):

Additional Remarks:

Public Benefit(s):
This Agreement is entered into between the NIH through the Office of Technology Transfer, NIH, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 U.S.A.; and the (“Licensee”), a corporation of , having an office at .

The NIH and the Licensee agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, the NIH investigators made inventions that may have commercial applicability.

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

1.3 The Secretary of HHS has delegated to the NIH 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 C.F.R. Part 404.

1.4 The NIH 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.

1.5 The 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

2.1 “Affiliate(s)” means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the Licensee. For this purpose, the term “control” shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.2 “Government” means the government of the United States of America.

2.3 “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 2.3(a):

(i) continuations-in-part of 2.3(a);
(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations; and

(iv) any reissues, reexaminations, and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions claimed in 2.3(a): all counterpart foreign applications and patents to 2.3(a) and 2.3(b), including those listed in Appendix A; and

(d) Licensed Patent Rights shall not include 2.3(b) or 2.3(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter of a claim in 2.3(a).

2.4 “Licensed Products” means tangible materials, identified in Appendix B, which, in the course of manufacture, use, sale, or importation 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 judgment of a court of competent jurisdiction.

2.5 “Licensed Processes” 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 judgment of a court of competent jurisdiction.

2.6 “Licensed Territory” means the geographical area identified in Appendix B.

2.7 “Licensed Fields of Use” means the field of use identified in Appendix B.

3. GRANT OF RIGHTS

3.1 The NIH hereby grants and the 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.

3.2 The Licensee has no right to sublicense.

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

3.4 The NIH acknowledges that information relating to the Licensed Patent Rights may be of assistance to the Licensee in its research efforts. Accordingly, the NIH shall consider reasonable requests by the Licensee for access to the inventors of the Licensed Patent Rights.

4. ROYALTIES

4.1 The Licensee agrees to pay the NIH a non-creditable, nonrefundable license issue royalty as set forth in Appendix C.

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4.2 The Licensee agrees to pay the NIH a nonrefundable annual royalty as set forth in Appendix C.

4.3 All royalties due under this Agreement shall be paid in U.S. dollars, net of all non-U.S. taxes, and payment options are listed in Appendix E. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due.

4.4 Additional royalties may be assessed by the NIH on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by the NIH of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the NIH from exercising any other rights it may have as a consequence of the lateness of any payment.

5. PERFORMANCE

5.1 Upon receipt and verification of the royalties due under Paragraphs 4.1 and 4.2, the NIH agrees, if Licensed Products are available to the NIH, to provide the Licensee, at the Licensee's expense, with samples of the Licensed Products to the individual and address listed in Appendix D and, at reasonable cost to the Licensee, to replace them in the event of their unintentional destruction. The Licensee agrees to retain control over the Licensed Products and shall not distribute or release them to others without the prior written consent of the NIH.

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

5.3 The Licensee agrees in its use of any Licensed Products provided by the NIH to comply with all applicable statutes, regulations, and guidelines, including NIH and HHS regulations and guidelines. The Licensee agrees not to use the Licensed Products for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The Licensee agrees not to use the Licensed Products for research involving human subjects or clinical trials outside of the United States without notifying the NIH, in writing, of this research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the NIH 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 this research or trials.

5.4 All plans and reports required by this Agreement shall be treated by the NIH as commercial and financial information obtained from a person and as privileged and confidential and, to the extent permitted by law, not subject to disclosure under the Freedom of Information Act, 5 U.S.C. §552.
6. **NEGATION OF WARRANTIES AND INDEMNIFICATION**

6.1 The **NIH** offers no warranties other than those expressly specified in Article 1.

6.2 The **NIH** 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.

6.3 **THE NIH 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 LICENSED PRODUCTS PROVIDED TO THE LICENSEE UNDER PARAGRAPH 5.1.**

6.4 The **NIH** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

6.5 The **Licensee** shall indemnify and hold the **NIH**, 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 the **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 Paragraph 5.1, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

6.6 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

7. **TERM, TERMINATION AND MODIFICATION OF RIGHTS**

7.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 8.8 are not fulfilled, and shall expire at the time specified in Appendix B, unless previously terminated under the terms of this Article 7.

7.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 7.3 and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, the **NIH** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the **Federal Debt Collection Act**.

7.3 The **NIH** shall specifically have the right to terminate this **Agreement** by written notice if the **Licensee**: 
(a) has not demonstrated that it is executing the research plan submitted with its application for a license or that it has not taken or cannot 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

(b) 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.

7.4 The NIH reserves the right according to 35 U.S.C. §209(d)(3) to terminate this Agreement if it is determined that this action is necessary to meet the requirements for public use specified by Federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the Licensee.

7.5 The Licensee shall have a unilateral right to terminate this Agreement by giving the NIH sixty (60) days written notice to that effect.

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

7.7 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 the modification. No modification shall be effective until a written amendment is signed by the signatories to this Agreement or their designees.

7.8 Within ninety (90) days of expiration, termination or term extension of this Agreement under this Article 7, a final report shall be submitted by the Licensee. The Licensee shall send the report to the NIH at the Mailing Address for Agreement notices indicated on the Signature Page.

(a) The report shall include, but not be limited to, progress on the research and development involving the Licensed Patent Rights, the Licensed Products or the Licensed Processes.

(b) Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty) due to the NIH shall become immediately due and payable upon termination or expiration. Unless otherwise specifically provided for under this Agreement, upon termination or expiration of this Agreement, the Licensee shall return all Licensed Products or other materials included within the Licensed Patent Rights to the NIH or provide the NIH with written certification of the destruction thereof.

(c) If the term of the Agreement is extended at the Licensee’s request, then the NIH and the Licensee will negotiate in good faith regarding the schedule for reports regarding the information required in 7.8(a);
(d) If the term of this Agreement is longer than ten (10) years, then the NIH may request a status update report after the fifth (5th) year of the Agreement; and

(e) The Licensee may not be granted additional NIH licenses if this reporting requirement is not fulfilled.

7.9 Paragraphs 4.3, 4.4, 5.4, 6.1-6.5, 7.6, 7.8 and 7.9 of this Agreement shall survive termination of this Agreement.

8. GENERAL PROVISIONS

8.1 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.

8.2 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.

8.3 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.

8.4 All Agreement 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 another 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.

8.5 This Agreement shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the Licensee’s Affiliate(s) without the prior written consent of the NIH. The parties agree that the identity of the parties is material to the formation of this Agreement and that the obligations under this Agreement are nondelegable.

8.6 The 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 materials and other commodities. The transfer of these items may require a license from the appropriate agency of the Government or written assurances by the Licensee that it shall not export these items to certain foreign countries without prior approval of the agency. The NIH neither represents that a license is or is not required or that, if required, it shall be issued.

8.7 The parties agree to attempt to settle amicably any controversy or claim arising under this Agreement or a breach of this Agreement, except for appeals of modification or termination decisions provided for in Article 7. The Licensee agrees first to appeal any such unsettled claims or controversies to the designated the NIH official or designee, whose decision shall be considered the final agency decision. Thereafter, the Licensee may exercise any administrative or judicial remedies that may be available.
8.8 The terms and conditions of this Agreement shall, at the NIH’s sole option, be considered by the NIH to be withdrawn from the Licensee’s consideration and the terms and conditions of this Agreement, and the Agreement itself to be null and void, unless this Agreement is executed by the Licensee and a fully executed original is received by the NIH within sixty (60) days from the date of the NIH signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE
NIH NON-EXCLUSIVE PATENT LICENSE AGREEMENT
FOR INTERNAL RESEARCH USE

FOR NIH:

by: __________ DRAFT ___________________________ 

Richard U. Rodriguez 
Director, Division of Technology Development and Transfer 
Office of Technology Transfer 
National Institutes of Health 

Date

Mailing Address or E-mail Address for Agreement notices and reports:

Chief, Monitoring & Enforcement Branch 
Office of Technology Transfer 
National Institutes of Health 
6011 Executive Boulevard, Suite 325 
Rockville, Maryland 20852-3804 U.S.A.

E-mail: LicenseNotices_Reports@mail.nih.gov

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

Licensee

by: _______ DRAFT ___________________________ 

Signature of Authorized Official 
Date

Printed Name

Title

I. Official and Mailing Address for Agreement notices:

Name

Title

Mailing Address

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II. Official and Mailing Address for Financial notices (Licensee’s contact person for royalty payments)

Name

Title

Mailing Address:

Email Address: ________________________________

Phone: ________________________________

Fax: ________________________________

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).
APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

I.

II.

III.
APPENDIX B – LICENSED PRODUCTS, PROCESSES, TERRITORY, FIELD OF USE AND TERMINATION

I. Licensed Products:

   (a)

II. Licensed Processes:

   (a)

III. Licensed Territory:

   (a)

IV. Licensed Fields of Use:

   (a)

V. Termination:

   (a) This Agreement shall expire ________ (X) years from the effective date as defined in Paragraph 7.1 unless previously terminated under Article 7.
APPENDIX C – ROYALTIES

Royalties:

I. The Licensee agrees to pay to the NIH a noncreditable, nonrefundable license issue royalty in the amount of ________ dollars ($X) within sixty (60) days from the effective date of this Agreement.

II. The Licensee agrees to pay to the NIH a nonrefundable annual royalty in the amount of ________ dollars ($X) as follows:

(a) The first annual royalty is due within sixty (60) days of the effective date of this Agreement and may be prorated according to the fraction of the calendar year remaining between the effective date of this Agreement and the next subsequent January 1; and

(a) Subsequent annual royalty payments are due and payable on January 1 of each calendar year.
APPENDIX D – SHIPPING INFORMATION

The Licensee’s Shipping Contact: information or questions regarding shipping should be directed to the Licensee’s Shipping Contact at:

___________________________________________  ______________________________
Shipping Contact’s Name                  Title

Phone: ( )  Fax: ( )  E-mail:________________________

Shipping Address: Name & Address to which Materials should be shipped (please be specific):

___________________________________________
Company Name & Department

Address:

___________________________________________

___________________________________________


The Licensee’s shipping carrier and account number to be used for shipping purposes:

___________________________________________
APPENDIX E – ROYALTY PAYMENT OPTIONS

The OTT License Number MUST appear on payments, reports and correspondence.

Automated Clearing House (ACH) for payments through U.S. banks only

The NIH encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: https://www.pay.gov. Locate the "NIH Agency Form" through the Pay.gov "Agency List”.

Electronic Funds Wire Transfers

The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE should be sent directly to the following account:

- **Beneficiary Account:** Federal Reserve Bank of New York or TREAS NYC
- **Bank:** Federal Reserve Bank of New York
- **ABA#** 021030004
- **Account Number:** 75080031
- **Bank Address:** 33 Liberty Street, New York, NY 10045
- **Payment Details:** License Number (L-XXX-XXXX)
  - Name of the Licensee

Drawn on a **foreign bank account** should be sent directly to the following account. Payment must be sent in **U.S. Dollars (USD)** using the following instructions:

- **Beneficiary Account:** Federal Reserve Bank of New York/ITS or FRBNY/ITS
- **Bank:** Citibank N.A. (New York)
- **SWIFT Code:** CITIUS33
- **Account Number:** 36838868
- **Bank Address:** 388 Greenwich Street, New York, NY 10013
- **Payment Details (Line 70):** NIH 75080031
  - License Number (L-XXX-XXXX)
  - Name of the Licensee

**Detail of Charges (line 71a):** Charge Our
Checks

All checks should be made payable to “NIH Patent Licensing”

Checks drawn on a U.S. bank account and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health (NIH)
P.O. Box 979071
St. Louis, MO 63197-9000

Checks drawn on a U.S. bank account and sent by overnight or courier should be sent to the following address:

US Bank
Government Lockbox SL-MO-C2GL
1005 Convention Plaza
St. Louis, MO 63101
Phone: 314-418-4087

Checks drawn on a foreign bank account should be sent directly to the following address:

National Institutes of Health (NIH)
Office of Technology Transfer
Royalties Administration Unit
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852