PUBLIC HEALTH SERVICE

BIOLOGICAL MATERIALS LICENSE AGREEMENT

This Agreement is based on the model Biological Material License Agreement adopted by the U.S. Public Health Service ("PHS") Technology Transfer Policy Board for use by components of the National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), and the Food and Drug Administration ("FDA"), which are agencies of the PHS within the Department of Health and Human Services ("HHS").

This Cover Page identifies the Parties to this Agreement:

The U.S. Department of Health and Human Services, as represented by

 [Insert the full name of the IC]

an Institute or Center (hereinafter referred to as the "IC") of the

[INSERT as appropriate: NIH, CDC, or FDA]

and

[Insert Company’s official name],

hereinafter referred to as the “Licensee”,

having offices at [Insert Company’s address],

created and operating under the laws of [Insert State of Incorporation].

Tax ID No.:______________________
1. Definitions:

(a) “Government” means the government of the United States of America.

(b) “FDA” means the Food and Drug Administration.

(c) “Materials” means the following biological materials including all progeny, subclones, and unmodified derivatives thereof: ______________________________________________________________, as described in ___________________________ and developed in the laboratory of __________________ at the IC.

(d) “Licensed Field of Use” means ___________________________________.

(e) “Licensed Products” means ________________________.

(f) “Net Sales” means the total gross receipts by the Licensee for sales of Licensed Products or from income from leasing, renting, or otherwise making Licensed Products available to others without sale or other dispositions transferring title, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the Licensee, or for the cost of collections.

2. The Licensee desires to obtain a license from the IC to use the Materials provided under this Agreement in its commercial research or product development and marketing activities. The Licensee represents that it has the facilities, personnel, and expertise to use the Materials or the Licensed Products for commercial purposes and agrees to expend reasonable efforts and resources to develop the Materials or the Licensed Products for commercial use or commercial research.

3. The IC hereby grants to the Licensee:

(a) a worldwide, non-exclusive license to make, have made, and use the Materials or the Licensed Products in the Licensed Field of Use; and

(b) a worldwide, non-exclusive license to sell and have sold, to offer to sell and to import the Licensed Products in the Licensed Field of Use.

4. In consideration of the grant in Paragraph 3, the Licensee hereby agrees to make the following payments to the IC:

(a) Within sixty (60) days of its execution of this Agreement, a noncreditable, nonrefundable license issue royalty of __________ dollars ($X);

(b) The first minimum annual royalty of __________ dollars ($XX) 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;
(c) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year;

(d) An earned royalty of ______________ percent (X%) of Net Sales, which shall be due and payable within sixty (60) days of the end of each calendar year; and

(e) All payments required under this Agreement shall be paid in U.S. dollars and payment options are listed in Appendix C. 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.

i) Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the Licensee; and

ii) Additional royalties may be assessed by the IC 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 IC of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the IC from exercising any other rights it may have as a consequence of the lateness of any payment.

5. Upon receipt by the IC of the license issue royalty and the prorated first year minimum annual royalty and verification of these royalties, the IC agrees to provide the Licensee with samples of the Materials, as available, and to replace these Materials, as available, at reasonable cost, in the event of their unintentional destruction. The IC shall provide the Materials to the Licensee at the Licensee’s expense and as specified in Appendix A.

6. The Licensee agrees to make written reports to the IC within sixty (60) days of December 31 for each calendar year. This report shall state: the number, description, and aggregate Net Sales of Licensed Products made, sold, or otherwise disposed of; the total gross income received by the Licensee from leasing, renting, or otherwise making Licensed Products available to others without sale or other disposition transferring title, during the calendar year; and the resulting calculation of earned royalties due to the IC pursuant to Paragraph 4(d) and as shown in the example in Appendix B. The Licensee shall submit each report to the IC at the Mailing Address for Agreement notices indicated on the Signature Page or electronically mailed to the email address indicated on the Signature Page.

7. The Licensee agrees to supply the laboratory of Dr. _____________ at the IC at no charge, reasonable quantities of Materials or the Licensed Products that the Licensee makes, uses, sells, or offers for sale or otherwise makes available for public use. The Licensee also agrees to supply, to the Mailing Address for Agreement notices indicated on the Signature Page, the Office of Technology Transfer, NIH with inert samples of the Licensed Products or their packaging for educational and display purposes only.

8. This Agreement shall become effective on the date when the last party to sign has executed this Agreement, unless the provisions of Paragraph 26 are not fulfilled, and shall expire __________________ (X) years from this effective date, unless previously terminated under the terms of Paragraphs 16 or 17.

9. As part of the Licensee’s performance under this Agreement, the Licensee agrees to make the Licensed Products available to the public within ________ (X) months from the effective date of this Agreement.
10. The **Licensee** agrees to retain control over the **Materials** and the **Licensed Products**, and not to distribute them to third parties without the prior written consent of the **IC** except as provided in Paragraph 3.

11. This **Agreement** does not preclude the **IC** from distributing the **Materials** or the **Licensed Products** to third parties for research or commercial purposes.

12. By this **Agreement**, the **IC** grants no patent rights expressly or by implication to any anticipated or pending **IC** patent applications or issued patents.

13. **NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS PROVIDED TO THE LICENSEE UNDER THIS AGREEMENT, OR THAT THE MATERIALS OR THE LICENSED PRODUCTS MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES.** The **Licensee** accepts license rights to the **Materials** and the **Licensed Products** “as is”, and the **IC** does not offer any guarantee of any kind.

14. **Licensee** agrees to indemnify and hold harmless the **Government** from any claims, costs, damages, or losses that may arise from or through the **Licensee's use of the Materials or the Licensed Products.** The **Licensee** further agrees that it shall not by its action bring the **Government** into any lawsuit involving the **Materials** or the **Licensed Products**.

15. The **Licensee** agrees in its use of the **Materials** or the **Licensed Products** to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use the **Materials** or 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 **Materials** or the **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying the **IC**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **IC** 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.

16. The **Licensee** may terminate this **Agreement** upon thirty (30) days written notice to the **IC** but only after sixty (60) days from the effective date of this **Agreement**.

17. The **IC** may terminate this **Agreement** if the **Licensee** is in default in the performance of any material obligation under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of written notice by the **IC** of the default.

18. Within thirty (30) days of the termination or expiration of this **Agreement**, the **Licensee** agrees to return all **Materials** and the **Licensed Products** to the **IC** or provide the **IC** with written certification of their destruction.

19. Within ninety (90) days of termination or expiration of this **Agreement**, the **Licensee** agrees to submit a final report to the **IC**, and to submit to the **IC** payment of any royalties due. The **Licensee** may not be granted additional **IC** licenses if this final reporting requirement is not fulfilled.

20. The **Licensee** is encouraged to publish the results of its research projects using the **Materials** or the **Licensed Products**. In all oral presentations or written publications concerning the **Materials** or the **Licensed Products**, the **Licensee** shall acknowledge the contribution of Dr. __________________________ at the **IC** supplying the **Materials**, unless requested otherwise by the **IC** or Dr. __________________________.
21. All plans and reports required by this Agreement shall be treated by the IC 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.

22. This Agreement shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this Agreement. The Licensee agrees to be subject to the jurisdiction of U.S. courts.

23. This Agreement constitutes the entire understanding of the IC and the Licensee and supersedes all prior agreements and understandings with respect to the Materials or the Licensed Products.

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

25. Paragraphs 4, 13, 14, 18, 19, 20, 21 and 25 of this Agreement shall survive termination or expiration of this Agreement.

26. The terms and conditions of this Agreement shall, at the IC’s sole option, be considered by the IC 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 IC within sixty (60) days from the date of the IC signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE
THE IC BIOLOGICAL MATERIALS LICENSE AGREEMENT

SIGNATURE PAGE

In Witness Whereof, the parties have executed this Agreement on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For the IC:

________________________          ____________
Name                        Date
Title
Office
National Institutes of Health

Address for Agreement notices and reports:

E-mail: LicenseNotices_Reports@mail.nih.gov (preferred)

Mail: License Compliance and Administration
      Monitoring & Enforcement
      Office of Technology Transfer
      National Institutes of Health
      6701 Rockledge Drive, Suite 700, MS 7788
      Bethesda, Maryland 20892 U.S.A.

(For courier deliveries please check https://www.ott.nih.gov/licensing/license-noticesreports)
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):

by:

___________________

DRAFT

Signature of Authorized Official

Date

___________________

Printed Name

___________________

Title

I. Official and Mailing Address for Agreement notices:

Name

Title

Mailing Address

Email Address: ____________________________

Phone: ____________________________

Fax: ____________________________

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

Name

Title

Mailing Address:
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) and/or imprisonment).
APPENDIX A – 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:

________________________________________

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APPENDIX B – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- License reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Name</th>
<th>Country</th>
<th>Units Sold</th>
<th>Gross Sales (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A</td>
<td>US</td>
<td>250</td>
<td>62,500</td>
</tr>
<tr>
<td>1</td>
<td>A</td>
<td>UK</td>
<td>32</td>
<td>16,500</td>
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<td>1</td>
<td>A</td>
<td>France</td>
<td>25</td>
<td>15,625</td>
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<tr>
<td>2</td>
<td>B</td>
<td>US</td>
<td>0</td>
<td>0</td>
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<tr>
<td>3</td>
<td>C</td>
<td>US</td>
<td>57</td>
<td>57,125</td>
</tr>
<tr>
<td>4</td>
<td>D</td>
<td>US</td>
<td>12</td>
<td>1,500</td>
</tr>
</tbody>
</table>

Total Gross Sales 153,250

Less Deductions:
- Freight 3,000
- Returns 7,000

Total Net Sales 143,250

- Royalty Rate 8%
- Royalty Due 11,460
- Less Creditable Payments 10,000

Net Royalty Due 1,460
APPENDIX C – ROYALTY PAYMENT OPTIONS
New Payment Options Effective March 2018

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

Credit and Debit Card Payments: Credit and debit card payments can be submitted for amounts up to $24,999. Submit your payment through the U.S. Treasury web site located at: https://www.pay.gov/public/form/start/28680443.

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

The IC 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/public/form/start/28680443. Please note that the IC "only" accepts ACH payments through this U.S. Treasury web site.

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:

Please provide the following instructions to your Financial Institution for the remittance of Fedwire payments to the NIH ROYALTY FUND:

<table>
<thead>
<tr>
<th>Fedwire Field Tag</th>
<th>Fedwire Field Name</th>
<th>Required Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>{1510}</td>
<td>Type/Subtype</td>
<td>1000</td>
</tr>
<tr>
<td>{2000}</td>
<td>Amount</td>
<td>(enter payment amount)</td>
</tr>
<tr>
<td>{3400}</td>
<td>Receiver ABA routing number*</td>
<td>021030004</td>
</tr>
<tr>
<td>{3400}</td>
<td>Receiver ABA short name</td>
<td>TREAS NYC</td>
</tr>
<tr>
<td>{3600}</td>
<td>Business Function Code</td>
<td>CTR (or CTP)</td>
</tr>
<tr>
<td>{4200}</td>
<td>Beneficiary Identifier (account number)</td>
<td>(enter 12 digit gateway account #) 875080031006</td>
</tr>
<tr>
<td>{4200}</td>
<td>Beneficiary Name</td>
<td>(enter agency name associated with the Beneficiary Identifier) DHHS / NIH (75080031)</td>
</tr>
<tr>
<td>{5000}</td>
<td>Originator</td>
<td>(enter the name of the originator of the payment) COMPANY NAME</td>
</tr>
<tr>
<td>{6000}</td>
<td>Originator to Beneficiary Information – Line 1</td>
<td>(enter information to identify the purpose of the payment) ROYALTY</td>
</tr>
<tr>
<td>{6000}</td>
<td>Originator to Beneficiary Information – Line 2</td>
<td>(enter information to identify the purpose of the payment) LICENSE NUMBER</td>
</tr>
<tr>
<td>{6000}</td>
<td>Originator to Beneficiary Information – Line 3</td>
<td>(enter information to identify the purpose of the payment) INVOICE NUMBER</td>
</tr>
<tr>
<td>{6000}</td>
<td>Originator to Beneficiary Information – Line 4</td>
<td>(enter information to identify the purpose of the payment)</td>
</tr>
</tbody>
</table>

Notes:
Drawn on a **foreign bank account** via FEDWIRE:

The following instructions pertain to the Fedwire Network. Deposits made in US Dollars (USD).

Should your remitter utilize a correspondent US domestic bank in transferring electronic funds, the following Fedwire instructions are applicable.

<table>
<thead>
<tr>
<th>Fedwire Field Tag</th>
<th>Fedwire Field Name</th>
<th>Required Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>{1510}</td>
<td>Type/Subtype</td>
<td>1000 (enter payment amount)</td>
</tr>
<tr>
<td>{2000}</td>
<td>Amount</td>
<td>(enter the US correspondent bank’s ABA routing number)</td>
</tr>
<tr>
<td>{3100}</td>
<td>Sender Bank ABA routing number</td>
<td></td>
</tr>
<tr>
<td>{3400}</td>
<td>Receiver ABA routing number*</td>
<td>021030004</td>
</tr>
<tr>
<td>{3400}</td>
<td>Receiver ABA short name</td>
<td>TREAS NYC</td>
</tr>
<tr>
<td>{3600}</td>
<td>Business Function Code</td>
<td>CTR (or CTP)</td>
</tr>
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<td>{4200}</td>
<td>Beneficiary Identifier (account number)**</td>
<td>(enter 12 digit gateway account #) 875080031006</td>
</tr>
<tr>
<td>{4200}</td>
<td>Beneficiary Name</td>
<td>(enter agency name associated with the Beneficiary Identifier) DHHS / NIH (75080031)</td>
</tr>
<tr>
<td>{5000}</td>
<td>Originator</td>
<td>(enter the name of the originator of the payment) COMPANY’S NAME</td>
</tr>
<tr>
<td>{6000}</td>
<td>Originator to Beneficiary Information – Line 1</td>
<td>(enter information to identify the purpose of the payment) ROYALTY</td>
</tr>
<tr>
<td>{6000}</td>
<td>Originator to Beneficiary Information – Line 2</td>
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<td>{6000}</td>
<td>Originator to Beneficiary Information – Line 4</td>
<td>(enter information to identify the purpose of the payment)</td>
</tr>
</tbody>
</table>

**Notes:**
*The financial institution address for Treasury’s routing number is 33 Liberty Street, New York, NY 10045.
**Anything other than the 12 digit gateway account # will cause the Fedwire to be returned – **SWIFT CODE: FRNYUS33**

**Agency Contacts:**
Office of Technology Transfer (OTT)  (301) 496-7057  OTT-Royalties@mail.nih.gov

**Checks**

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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  
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  
Office of Technology Transfer  
License Compliance and Administration  
Royalty Administration  
6701 Rockledge Drive  
Suite 700, MSC 7788  
Bethesda, Maryland 20892