This Agreement is based on the model Biological Materials Internal Use 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) “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.
   (c) “Licensed Products” means ________________________.

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 non-exclusive license, within its research facilities, to make, have made, use, but not to sell the Materials or the Licensed Products.

4. In consideration of the grant in Paragraph 3, the Licensee 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
   (d) All payments required under this Agreement shall be paid in U.S. dollars and payment options are listed in Appendix B. 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 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. This Agreement shall become effective on the date when the last party to sign has executed this Agreement, unless the provisions of Paragraph 23 are not fulfilled, and shall expire ________ (X) years from this effective date, unless previously terminated under the terms of Paragraphs 13 or 14.

7. 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.

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

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

10. 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 “as is”, and the IC does not offer any guarantee of any kind.

11. The 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 Government into any lawsuit involving the Materials or the Licensed Products.

12. 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.

13. 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.

14. 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.

15. 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.

16. Within ninety (90) days of termination, expiration or term extension of this Agreement, the Licensee agrees to submit a report to the IC, and to submit to the IC payment of any royalties due.
(a) The report shall include, but not be limited to, progress on the research and development involving the Materials or the Licensed Products and use of the Materials or the Licensed Products. The Licensee shall send the report to the IC at the Mailing Address for Agreement notices indicated on the Signature Page;

(b) If the term of the Agreement is extended at the Licensee’s request, then the IC and the Licensee will negotiate in good faith regarding the schedule for reports regarding the information required in 16(a);

(c) If the term of this Agreement is longer than ten (10) years, then the IC may request a status update report after the fifth (5th) year of the Agreement; and

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

17. 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.

18. 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. ________________ and the HHS agency supplying the Materials, unless requested otherwise by the IC or Dr. ________________.

19. 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.

20. 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.

21. 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, 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.

22. Paragraphs 10, 11, 15, 16, 17, 18 and 22 of this Agreement shall survive termination or expiration of this Agreement.

23. 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.
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

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

License Compliance and Administration
Monitoring & Enforcement
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.):

by:

__________________________
Signature of Authorized Official  Date

Printed Name

Title

1. Official and Mailing Address for Agreement notices:

__________________________
Name

__________________________
Title

Mailing Address
II. Official and Mailing Address for Financial notices (The 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 United States 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:

____________________________________________________
APPENDIX B – 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](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](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:
*The financial institution address for Treasury’s routing number is 33 Liberty Street, New York, NY 10045.*
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>
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</thead>
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<td>{1510}</td>
<td>Type/Subtype</td>
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<tr>
<td>{2000}</td>
<td>Amount</td>
<td>(enter payment amount)</td>
</tr>
<tr>
<td>{3100}</td>
<td>Sender Bank ABA routing number</td>
<td>(enter the US correspondent bank’s ABA routing number)</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 #)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>875080031006</td>
</tr>
<tr>
<td>{4200}</td>
<td>Beneficiary Name</td>
<td>(enter agency name associated with the Beneficiary Identifier)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DHHS / NIH (75080031)</td>
</tr>
<tr>
<td>{5000}</td>
<td>Originator</td>
<td>(enter the name of the originator of the payment)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>COMPANY’S NAME</td>
</tr>
<tr>
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<td>Originator to Beneficiary Information – Line 1</td>
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<tr>
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<td>ROYALTY</td>
</tr>
<tr>
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<td>Originator to Beneficiary Information – Line 2</td>
<td>(enter information to identify the purpose of the payment)</td>
</tr>
<tr>
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<td>LICENSE NUMBER</td>
</tr>
<tr>
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<td>Originator to Beneficiary Information – Line 3</td>
<td>(enter information to identify the purpose of the payment)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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:
*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
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:

A -XXX-201X
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  
6011 Executive Boulevard  
Suite 325, MSC 7660  
Rockville, Maryland 20852