PUBLIC HEALTH SERVICE

COMMERCIAL EVALUATION LICENSE AGREEMENT

This Agreement is based on the model Commercial Evaluation 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.:____________________
L#:

1. Definitions:
   (a) “Government” means the government of the United States of America.
   (b) “Licensed Patent Rights” means PCT or U.S. patent application(s) (including provisional patent application(s)) or patents and all foreign counterparts as follows: U.S. Patent Application Serial No. XX/XXX,XXX or U.S. Provisional Patent Application Serial No. XX/XXX,XXX, filed ________________, entitled ________________________.
   (c) “Materials” means ______________________________, including all progeny, subclones, or unmodified derivatives thereof.
   (d) “Licensed Products” means ________________________ and Materials made by the Licensee within the scope of the Licensed Patent Rights.
   (e) “Licensed Field of Use” means ________________________________.

2. The Licensee desires to obtain a license to evaluate the commercial applications of the Materials and the Licensed Products and any inventions claimed in the Licensed Patent Rights.

3. The Licensee intends to conduct laboratory experiments under this Agreement to evaluate the suitability for commercial development of inventions encompassed by the Licensed Patent Rights, Materials or Licensed Products in the Licensed Field of Use.

4. The Licensee represents that it has the facilities, personnel, and expertise to evaluate the commercial applications of the Materials and the Licensed Products and the inventions encompassed by the Licensed Patent Rights, and that it shall expend reasonable efforts and resources on research and development of potential commercial products using the Materials or the Licensed Products and the inventions encompassed by the Licensed Patent Rights.

5. The IC hereby grants to the Licensee a nonexclusive license for evaluation purposes only, within its research facilities, to make and use but not to sell the Materials or the Licensed Products and products and processes encompassed within the scope of a claim in the Licensed Patent Rights in the Licensed Field of Use. The Licensee agrees that any commercial or industrial use or sale of any such products or processes, including any formalized in-house screening programs, other than for evaluation purposes, shall be made only pursuant to the terms of a commercialization license to be negotiated in good faith by the parties. The rights provided herein are provided for the evaluation of commercial applications only and not for commercial use.

6. The IC agrees, after receipt and verification of the license issue royalty, as required by Paragraph 9(a), to provide the Licensee with samples of the Materials, as available, and to replace the Materials, as available, and 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.

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 Licensed Products to third parties for research or commercial purposes.

9. In consideration of the grant in Paragraph 5:

(a) The Licensee hereby agrees to pay the IC a license issue royalty of _______ dollars ($X) and payment is due within sixty (60) days of the effective date of this Agreement.

(b) This license issue royalty 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.

10. This Agreement shall become effective on the date when the last party to sign has executed this Agreement, unless the provisions of Paragraph 24 are not fulfilled, and shall expire _________ (X) months from its effective date. Within thirty (30) days of the termination or expiration of this Agreement, the Licensee shall return all Materials and Licensed Products to the IC or provide the IC with written certification of their destruction, unless the Licensee has executed a commercialization license for the Licensed Patent Rights.

11. In the event that 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 of the default, the IC may terminate this Agreement by written notice.

12. The Licensee acknowledges that third parties also may be evaluating the Licensed Patent Rights, the Licensed Products, or the Materials for a variety of commercial purposes, and no guarantee can be made, should the Licensee apply for a license, that such a license would be available for any particular field of use. The IC agrees to notify the Licensee promptly if it receives from another company an exclusive license application in the Licensed Field of Use described in Paragraph 3.

13. The Licensee is encouraged to publish the results of its research projects using the Licensed Products or the Materials. In all oral presentations or written publications concerning the Licensed Products or the Materials, the Licensee shall acknowledge the contribution by the named inventors to the Licensed Products or the Materials, unless requested otherwise by the IC or the named inventors.
14. The Licensee agrees to submit in confidence a final report to the IC within thirty (30) days of termination or expiration of this Agreement outlining in general its results of commercial evaluation of the Licensed Patent Rights, the Licensed Products, or the Materials provided by this Agreement. The Licensee shall submit the 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. The Licensee may not be granted additional IC licenses if this final reporting requirement is not fulfilled.

15. The IC agrees, to the extent permitted by law, to treat the Licensee's written information about the Licensed Patent Rights, the Licensed Products, or the Materials that is submitted in the final report required under Paragraph 14 and stamped “CONFIDENTIAL” as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the IC under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d). Such confidentiality shall not extend to any part of the information that was previously known to the IC, that is or becomes publicly available, or that is disclosed to the IC by a third party without an obligation of confidentiality.

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

17. The Licensee agrees to indemnify and hold harmless the IC and the Government from any claims, costs, damages, or losses that may arise from the practice of the Licensed Patent Rights or through the use of the Licensed Products or the Materials.

18. Neither party shall have any obligation to take any action with regard to an infringement of Licensed Patent Rights by a third party.

19. The Licensee agrees in its use of any 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.

20. 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.

21. This Agreement constitutes the entire understanding of the IC and the Licensee and supersedes all prior agreements and understandings with respect to the Licensed Patent Rights, the Materials and the Licensed Products.
22. 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.

23. Paragraphs 9, 10, 13, 14, 15, 16, 17 and 23 of this Agreement shall survive termination of this Agreement.

24. 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
IC COMMERCIAL EVALUATION 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:

DRAFT

Name  

Title  

Office  

National Institutes of Health

Address for Agreement notices and reports:

E-mail: LicenseNotices.Reporting@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)

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, MS 7788  

Bethesda, Maryland 20892 U.S.A.

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

A-XXX-201X

CONFIDENTIAL  

NIH Commercial Evaluation License Agreement (CEL)  

Model 10-2015  Page 6 of 12  [Draft/Final]  [Company]  [Date]
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:

______________________________
______________________________
______________________________
______________________________

______________________________
Email 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:

<table>
<thead>
<tr>
<th>Shipping Contact’s Name</th>
<th>Title</th>
</tr>
</thead>
</table>

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>
### Fedwire Field Tag | Fedwire Field Name | Required Information
--- | --- | ---
{1510} | Type/Subtype | 1000
{2000} | Amount | (enter payment amount)
{3100} | Sender Bank ABA routing number | (enter the US correspondent bank’s ABA routing number)
{3400} | Receiver ABA routing number* | 021030004
{3400} | Receiver ABA short name | TREAS NYC
{3600} | Business Function Code | CTR (or CTP)
{4200} | Beneficiary Identifier (account number)** | (enter 12 digit gateway account #) 875080031006
{4200} | Beneficiary Name | (enter agency name associated with the Beneficiary Identifier) DHHS / NIH (75080031)
{5000} | Originator | (enter the name of the originator of the payment) COMPANY’S NAME
{6000} | Originator to Beneficiary Information – Line 1 | (enter information to identify the purpose of the payment) ROYALTY
{6000} | Originator to Beneficiary Information – Line 2 | (enter information to identify the purpose of the payment) LICENSE NUMBER
{6000} | Originator to Beneficiary Information – Line 3 | (enter information to identify the purpose of the payment) INVOICE NUMBER
{6000} | Originator to Beneficiary Information – Line 4 | (enter information to identify the purpose of the payment)

### 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:

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
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852