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.:_____

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. 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 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:

_____ **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:

_____

_____

_____

_____

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) 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.**

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**.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	**1000**
{2000}	Amount	*(enter payment amount)*
{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 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)*

Fedwire Field Tag	Fedwire Field Name	Required Information
Notes: *The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.		

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

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.

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