PUBLIC HEALTH SERVICE

COMMERCIAL EVALUATION - BIOLOGICAL MATERIALS LICENSE AGREEMENT

This **Agreement** is based on the model Commercial Evaluation - 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) "**Benchmark Royalty**" means a royalty due upon the six (6) month anniversary of the **Effective Date**. The **Benchmark Royalty** will be payable upon the six (6) month anniversary of the **Effective Date** unless **Licensee** provides notice of termination of this **Agreement** at least thirty (30) days prior to the due date of the **Benchmark Royalty**.

(b) "**Effective Date**" means the date when the last party to sign has executed this **Agreement**.

(c) "**FDA**" means the Food and Drug Administration.

(d) "**Government**" means the government of the United States of America.

(e) "**Licensed Field of Use**" means the use of **Licensed Products** for internal research purposes only. The **Licensed Field of Use** specifically excludes the sale or other distribution of the **Materials** or the **Licensed Products** for any purpose, including the use of the **Materials** or the **Licensed Products** in a fee-for-service assay.

(f) "**Licensed Products**" means the _____ produced by the **Materials** and compositions incorporating the _____ produced by the **Materials**.

(g) "**Materials**" means the following biological materials, including all progeny, subclones, or unmodified derivatives thereof:
_____, as described in
_____
_____ and developed in the laboratory of
_____.

(h) "**Materials Royalty**" means a royalty due upon the six (6) month anniversary of the **Effective Date** when additional **Materials** are required.

2. **Licensee** desires to obtain:

(a) a license from **IC** to use the **Materials** provided under this **Agreement** to evaluate the **Licensed Products** for a period of up to six (6) months from the **Effective Date**; and

(b) a license from **IC** to use the **Materials** or the **Licensed Products** in its commercial research or product development and marketing activities upon the payment of the **Benchmark Royalty**.

3. **Licensee** intends:

(a) to conduct laboratory experiments under this **Agreement** to evaluate the suitability of the **Licensed Products** in the **Licensed Field of Use**; and

(b) to continue to use the **Materials** or the **Licensed Products** in the **Licensed Field of Use** only upon payment of the **Benchmark Royalty**.

4. **Licensee** represents that it has the facilities, personnel, and expertise to use the **Materials** and the **Licensed Products**, and agrees to expend reasonable efforts and resources on research and development of the **Licensed Products** unless this **Agreement** is otherwise terminated or expired.

5. **IC** hereby grants to **Licensee** a non-exclusive license, within its research facilities, to make, have made and use, *but not to sell*, the **Materials** or the **Licensed Products** within the **Licensed Field of Use**. **Licensee** agrees that the continued use of the **Materials** or the **Licensed Products** after the six (6) month anniversary of the **Effective Date** will occur only pursuant to the payment of the **Benchmark Royalty**. The continued use of the **Materials** or the **Licensed Products** after the six (6) month anniversary of the **Effective Date** without payment of the **Benchmark Royalty** will be considered a material breach of this **Agreement**.

6. **Licensee** hereby agrees to pay **IC**:

   (a) A non-creditable, non-refundable license issue royalty of _____ dollars ($X) no later than sixty (60) days following the **Effective Date**.

   (b) A non-creditable, non-refundable **Benchmark Royalty** of _____ dollars ($X) no later than six (6) months after the **Effective Date**. This **Benchmark Royalty** is due unless **Licensee** indicates to **IC** that it will terminate the **Agreement** in writing and at least thirty (30) days prior to the due date of the **Benchmark Royalty**.

   (c) (*only if additional **Materials** are required*) A non-creditable, non-refundable **Materials Royalty** of _____ dollars ($X) if additional **Materials** are required at the six (6) month anniversary of the **Effective Date**. The **Materials Royalty** is due only if **IC** has been requested to send the additional **Materials**.

   (d) A non-refundable annual royalty of _____ dollars ($X), as follows:

      i) The first annual royalty is due and payable no later than the six (6) month anniversary of the **Effective Date** and may be prorated according to the fraction of the calendar year remaining between the six (6) month anniversary of the **Effective Date** and the next subsequent January 1.

      ii) Each subsequent annual royalty shall be due and payable on January 1 of each calendar year.

      iii) Each annual royalty is due unless **Licensee** indicates to **IC** that it will terminate the **Agreement** in writing and at least thirty (30) days prior to its due date.

   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.

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

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

7. **IC** agrees, upon receipt and verification of the license issue royalty, as required by Paragraph 6(a), to provide **Licensee** with XXX (*please enter quantity*) of the **Materials**, as available, and to replace the **Materials**, as available and at reasonable cost, in the event of their unintentional destruction. [*If additional **Materials** are required upon the six (6) month anniversary of the **Effective Date**, **IC** agrees, after receipt and verification of the **Materials Royalty**, as required by Paragraph 6(c), to provide **Licensee** with an additional XXX (please enter quantity) of the **Materials**, as available, and to replace the **Materials**, as available and at reasonable cost, in the event of their unintentional destruction* (only if necessary)]. **IC** shall provide the **Materials** to **Licensee** at **Licensee's** expense and as specified in Appendix A.

8. This **Agreement** shall become effective on the **Effective Date** unless the provisions of Paragraph 26 are not fulfilled, and shall expire exactly ____ (X) years after the **Effective Date**.

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

10. **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 **IC**.

11. This **Agreement** does not preclude **IC** or the **FDA** from distributing the **Materials** or the **Licensed Products** to third parties for research or commercial purposes. **Licensee** acknowledges that third parties also may be evaluating the **Licensed Products** or the **Materials** for a variety of commercial purposes.

12. By this **Agreement**, **IC** grants no patent rights expressly or by implication to any anticipated or pending **IC** or **FDA** 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** OR THE **LICENSED PRODUCTS** PROVIDED TO **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **MATERIALS** OR **LICENSED PRODUCTS** MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. **Licensee** accepts license rights to the **Licensed Products** and the **Materials** "as is" and **IC** does not offer any guarantee of any kind.

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

15. **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. **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. **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 **IC**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **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**.

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 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 or electronically mailed to the email address 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 18(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 (5^{th}) year of the **Agreement**; and

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

19. 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

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. _____ and the **HHS** agency supplying the **Materials**, unless requested otherwise by the **IC** or the **FDA** or Dr. _____.

21. **Licensee** agrees to supply the laboratory of Dr. _____, at **IC**, at no charge, reasonable quantities of **Materials** or the **Licensed Products** that **Licensee** makes or uses, provided that either **IC** or Dr. _____ makes a request for said **Materials** or **Licensed Products**.

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**. **Licensee** agrees to be subject to the jurisdiction of U.S. courts.

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

24. 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**.

25. Paragraphs 6, 9, 13, 14, 18, 19, 20 and 25 of this **Agreement** shall survive termination or expiration of this **Agreement**.

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

SIGNATURES BEGIN ON NEXT PAGE

NIH COMMERCIAL EVALUATION AND BIOLOGICAL MATERIALS-INTERNAL USE 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 **IC**:

_____**DRAFT**_____ _____

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

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

Checks are no longer accepted.
New Payment Options Effective September 2024

The License Number (L-xxx-xxxx-x) MUST appear on payments, reports, and correspondence.

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

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.**

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 (L-xxx-xxxx-x)**
{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.

Drawn on a **non-US 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}{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 (L-xxx-xxxx-x)**
{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

Automated Clearing House (ACH)

The IC encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). ACH payments can be submitted by two methods: Pay.gov (for US banks only) or standard ACH payment (US and non-US banks accepted).

Pay.gov: ACH payments can be submitted for US banks only. Submit your ACH payment through the U.S. Treasury web site located at: https://www.pay.gov/public/form/start/28680443.

Standard ACH: credits can be submitted for payments up to $99,999,999 for US and International banks. Please provide the following instructions to your Financial Institution for the remittance of Automated Clearing House (ACH) credits to the United States Department of Health of Human Services - National Institutes of Health (NIH):

Drawn on a **US** or **non-US bank account** via standard ACH:

NACHA Record Type Code	NACHA Field	NACHA Data Element Name	Required Information
5	3	Company Name	*(enter the name of the payor)*
5	6	Standard Entry Class Code	**CTX**
5	9	Effective Entry Date	*(enter intended settlement date)*
6	2	Transaction Code*	**22**
6	3 & 4	Receiving DFI Identification (ABA routing #)	**051036706**
6	5	DFI Account Number	**875080031006**
6	6	Amount	*(enter payment amount)*
6	8	Receiving Company Name	*(enter the identifying information)*
7	3	Payment Related Information	*(see format instructions below)*

Additional Payment Related Information should be included in NACHA Record 7 Field 3 and must conform to the ANSI ASC X12 standards using the EDI 820 Transaction Set Data Segments. A sample format follows.

Segment Contents	Element Descriptions
RMR*AR*License number**Amount being paid\N1*8R*Licensee Name**RMR*AR*license number 2**Amount being Paid 2\N1*8R*Licensee Name2**	DATA SEGMENT - Remittance Advice Accounts Receivable **RMR** * *(delimiter)* Reference Identification Qualifier: **AR** Accounts Receivable Number * *(delimiter)* **License number** (L-xxx-xxxx-x) * *(delimiter)* * *(delimiter)* Monetary Amount: Amount being paid \ *(segment terminator)* DATA SEGMENT – Name: **N1** * *(delimiter)* Entity Identifier Code: **8R** Identifies customer * *(delimiter)* Name: **Licensee name** \ *(segment terminator)*
Example: Licensee LLC with Licensee number L-xxx-20xx-x pays $1,000.00 *RMR*AR*L-xxx-20xx-x**1000.00\N1*8R*Licensee LLC* \	

ACH debits are not permitted to this ABA routing number. All debits received will be automatically rejected/returned.

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