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 invoiced amount to a third party for sales of **Licensed Products** by or on behalf of the **Licensee** and from leasing, renting, or otherwise making **Licensed Products** available to others, less returns and allowances, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately listed on the invoice), and cash discounts in amounts not to exceed 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 sublicensees and on its payroll, payments for any service received, or for the cost of collections. **Net Sales** for any sale or disposition of **Licensed Products** invoiced at zero or not invoiced shall be calculated at the average invoiced amount to a third party.

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 s**hall 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**:

_____**DRAFT**_____ _____

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:

_____

_____

_____

_____

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 – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- License reference number (L-XXX-20XX-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

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

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

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