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 25 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;

   (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 (5th) year of the **Agreement**; and

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

19. 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. ___________.

20. **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**.

21. 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.
22. 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.

23. 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.

24. Paragraphs 6, 9, 13, 14, 18, 19 and 24 of this Agreement shall survive termination or expiration of this Agreement.

25. 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
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:

_____________________________ _______________
Name Date
Title
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 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
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

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 $29,999. 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 should be sent directly to the following account:

- **Beneficiary Account:** Federal Reserve Bank of New York or TREAS NYC
- **Bank:** Federal Reserve Bank of New York
- **ABA#** 021030004
- **Account Number:** 75080031
- **Bank Address:** 33 Liberty Street, New York, NY 10045
- **Payment Details:** License Number (L-XXX-XXXX)
  - Name of the Licensee

Drawn on a **foreign bank account** should be sent directly to the following account. Payment must be sent in **U.S. Dollars (USD)** using the following instructions:

- **Beneficiary Account:** Federal Reserve Bank of New York/ITS or FRBNY/ITS
- **Bank:** Citibank N.A. (New York)
- **SWIFT Code:** CITIUS33
- **Account Number:** 36838868
- **Bank Address:** 388 Greenwich Street, New York, NY 10013
- **Payment Details (Line 70):**
  - **NIH** 75080031
  - **License Number (L-XXX-XXXX)**
  - **Name of the Licensee**
- **Detail of Charges (line 71a):** Charge Our

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

A-XXX-201X

CONFIDENTIAL
NIH Model Commercial Evaluation and Biological Materials-Internal Use License Agreement (CEL-BML-Internal Use Only)
Model 10-2015 Page 10 of 11 [Draft/Final] [Company] [Date]
FOR NEGOTIATION PURPOSES ONLY
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