

PUBLIC HEALTH SERVICE

BIOLOGICAL MATERIALS LICENSE AGREEMENT
FOR LICENSEE'S INTERNAL USE ONLY

This **Agreement** is entered into between the National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), or the Food and Drug Administration ("FDA"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**DHHS**") through the Office of Technology Transfer, National Institutes of Health, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and _____ ("**Licensee**"), a corporation of _____, having an office at _____.

1. Definitions:

- a. "**Materials**" means the following biological materials including all progeny, subclones, and derivatives thereof:

as described in

and developed in the laboratory of
_____.

- b. "**Licensed Products**" means _____.

2. **Licensee** wishes to obtain a license from **PHS** to use the **Materials** provided under this **Agreement** in its commercial research or product development and marketing activities. **Licensee** represents that it has the facilities, personnel, and expertise to use the **Materials** for commercial purposes and agrees to expend reasonable efforts and resources to develop the **Materials** for commercial use and/or commercial research.

3. **PHS** hereby grants to **Licensee** a worldwide, non-exclusive license to make, have made, use, but not to sell the **Materials**.

4. In consideration of the grant in Paragraph 3 above, **Licensee** hereby agrees to make the following payments to **PHS**:

- a. Within 30 days of its execution of this **Agreement**, a noncreditable, nonrefundable license issue royalty of _____ Dollars (\$_____).
- b. A nonrefundable annual royalty of _____ Dollars (\$_____) which shall be due and payable on January 1 of each calendar year. The annual royalty for the first calendar year of this **Agreement** is due and payable within thirty (30) days from 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.

All payments required under this **Agreement** shall be paid in U.S. dollars. 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. All checks and bank drafts shall be drawn on United States banks and shall be payable, as appropriate, to "NIH/Patent Licensing." All such payments

shall be sent to the following address: NIH, P.O. Box 360120, Pittsburgh, PA 15251-6120. 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**. Interest and penalties may be assessed by **PHS** on any overdue payments in accordance with the Federal Debt Collection Act. The payment of such late charges shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

5. Upon receipt by **PHS** of the license issue royalty, **PHS** agrees to provide **Licensee** with samples of the **Materials**, excluding progeny, subclones, and derivatives thereof ("**Supplied Materials**"), as available, and to replace such **Supplied Materials**, as available and at reasonable cost, in the event of their unintentional destruction.
6. **Licensee** agrees to make written reports to **PHS** within sixty (60) days after the end of each calendar year. These reports shall include, but not be limited to, progress on the research and development involving the **Materials** and use of the **Materials**.
7. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement** and shall expire _____ () years from this effective date, unless previously terminated under the terms of Paragraphs 14 or 15 below.
8. **Licensee** agrees to retain control over the **Materials**, and not to distribute them to third parties without the prior written consent of **PHS**.
9. **Licensee** agrees that this **Agreement** does not preclude **PHS** from distributing the **Materials** to third parties for research or commercial purposes.
10. By this **Agreement**, **PHS** grants no patent rights expressly or by implication to any anticipated or pending **PHS** patent applications or issued patents.
11. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE **MATERIALS** PROVIDED TO **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **MATERIALS** MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. **Licensee** accepts license rights to the **Materials** "as is", and **PHS** does not offer any guarantee of any kind.
12. **Licensee** agrees to indemnify and hold harmless the United States Government from any claims, costs, damages, or losses that may arise from or through **Licensee's** use of the **Materials**. **Licensee** further agrees that it will not by its action bring the United States Government into any lawsuit involving the **Materials**.
13. **Licensee** agrees in its use of any **PHS**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **DHHS** 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 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the **Materials** or **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** 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.
14. **Licensee** may terminate this **Agreement** upon sixty (60) days written notice to **PHS**.

15. **PHS** may terminate this **Agreement** if **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 **PHS** of such default.
16. Upon termination or expiration of this **Agreement**, **Licensee** agrees to return all **Materials** to **PHS**, or provide **PHS** with certification of their destruction.
17. Within ninety (90) days of termination or expiration of this **Agreement**, **Licensee** agrees to submit a final report to **PHS**, and to submit to **PHS** payment of any royalties due.
18. **Licensee** is encouraged to publish the results of its research projects using the **Materials**. In all oral presentations or written publications concerning the **Materials** or **Licensed Products**, **Licensee** will acknowledge the contribution of Dr. _____ and the **PHS** agency supplying the **Materials**, unless requested otherwise by **PHS** or Dr. _____.
19. 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 will preempt any conflicting or inconsistent provisions in this **Agreement**. **Licensee** agrees to be subject to the jurisdiction of U.S. courts.
20. This **Agreement** constitutes the entire understanding of **PHS** and **Licensee** and supersedes all prior agreements and understandings with respect to the **Materials**.
21. 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, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
22. Paragraphs 11, 12, and 18 of this **Agreement** shall survive termination or expiration of this **Agreement**.

SIGNATURES BEGIN ON NEXT PAGE

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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 **PHS**:

Jack Spiegel, Ph.D. _____ Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address for Notices:

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

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

Official and Mailing Address for Notices:

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).