MEDICAL TECHNOLOGY TRANSFER

USAMRMC CONTROL NUMBER:

DEPARTMENT OF THE ARMY CONROL NUMBER:

U. S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
BIOLOGICAL MATERIALS LICENSE AGREEMENT

This Agreement is entered into between the ***[USAMRMC Laboratory Name]*** (hereinafter **LICENSOR**") a subordinate Laboratory of United States Army Medical Research and Materiel Command ("USAMRMC"), located at ***[Street or location address of Laboratory]*** and ***[Company Name]***, (hereinafter ***[Company Name];*** **LICENSEE**"), a ***[Corporate type]*** corporation, having its principal place of business at ***[Address]***.

Under the authority of 15 United States Code (U.S.C.) 3701 et seq., 35 U. S. C. Sections 200 - 210, and 37 Code of Federal Regulations (CFR), Chapter IV (together with any amendments and the underlying rules and regulations now or hereafter promulgated collectively, the ***"Federal Technology Transfer Act"*** or the ***("FTTA"), [Laboratory Name]*** has the authority to enter into this Biological Material License Agreement.

BACKGROUND: ***[A description of the product and the use to which company will apply it; any reference to MRMC patent docket #/invention disclosure #; keep information in this section general]***

1. Definitions:

(a) ***"Affiliate(s)"*** means any corporation or other legal entity that controls, is controlled by, or is under common control with LICENSEE. For purposes of this definition, "control" (including, with correlative means, the terms "controlled by" and "under common control with"), means, whether de jure or de facto, the ownership, directly or indirectly, of more than fifty perfect (50%) of the outstanding equity securities of a corporation which are entitled to vote in the election of its Board of Directors or more than fifty percent (50%) interest in the net assets or profits of an entity which is not a corporation. For purposes of this definition, Affiliates shall include those Affiliates that are, or will become, Sublicensees under this Agreement and LICENSEE shall initially and continuously identify, designate and update its relationship with each Sublicensees and each Affiliate.

(b) ***"Effective Date"*** is the date that the execution fee is received by Defense Finance Accounting Service (DFAS). Use if an execution payment is required. If no payment use, ***"Execution Date"*** means the date of last signature to this Agreement.

(c) ***"Licensed Products"*** means ***[describe the product] identify product].***

(d) ***"Licensed Field of Use"*** means ***[describe the use].***

(e) ***"Materials and/or Methods"*** means the following biological material including all related information/descriptions ***[including clones, subclones, progeny, derivatives, composition, and know-how, etc]***.

(f) ***"Net Sales"*** means the actual gross amount billed, invoiced, charged or received on sales or transfers of any Licensed Products by LICENSEE or its Affiliates to any and all unaffiliated person(s), or in the event of disposal of any Licensed Products other than as scrap prior to shipment from its place of manufacture or predisposal storage, or other than by sales, the amount billed, invoiced, charged or received on sales or transfers for a like quantity and quality of Licensed Products to unaffiliated persons on or about the time of such disposal, less:

(i) trade, cash and quantity discounts, including charge backs, rebates, premiums, allowances and any other deduction actually granted to the unaffiliated person (not to exceed the original billing);

(ii) sales and excise taxes and duties and any other governmental charges imposed upon the importation, use or sale of the Licensed Products actually charged to the unaffiliated person;

(iii) freight, insurance and other transportation charges actually charged to the unaffiliated person; and

(iv) amounts repaid or credited (not to exceed the original billing) by reason of rejections, defects, outdating, price differences, recalls, or returns, or because of retroactive price reductions, or due to governmental laws or regulations, requiring rebates actually granted to the unaffiliated person.

The cumulative total of deductions specified above shall not decrease Net Sales by more than one-third compared to Net Sales calculated without consideration of these deductions.

For purposes of calculating Net Sales for any reporting period, any and all deductions used in calculating Net Sales are allowable only to the extent that they have already been included in the amounts billed, invoiced, charged or received or granted on the sales or transfers of Licensed Products by LICENSEE or its Affiliates to unaffiliated persons in bona fide arms' length transactions. Calculation of Net Sales shall be in accordance with generally accepted accounting principles. Sales or transfers of Licensed Products between or among LICENSEE and its Affiliate(s) shall be excluded from the computation of Net Sales except where such Affiliate(s) are end users, but Net Sales shall include the subsequent final sales or transfers to unaffiliated persons by such Affiliate(s), if not end users.

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

3. LICENSOR hereby grants to LICENSEE:

   (a) a **[worldwide]**, **[non-exclusive/exclusive]** license to make, have made, and use the Materials and/or Methods or the Licensed Products; and

   (b) a **[worldwide]**, **[non-exclusive/exclusive]** license to sell and have sold, to offer to sell and to import the Licensed Products in the Field(s) of Use.

4. In consideration of the grant in Paragraph 3, LICENSEE hereby agrees to make the following payments to LICENSOR according to the following schedule:

   (a) An initial execution fee is due within forty-five (45) days of execution. The terms of the License Agreement are as follows

      (i) A one-time execution fee of ***[$ x]*.**

      (ii) LICENSEE shall pay LICENSOR an annual royalty of *[X.X]* % of Net Sales for the Materials and/or Methods Used in ***[Licensed Products]***.

      (iii) A nonrefundable minimum annual payment of ***[X dollars]*** to be credited against the annual Net Sales royalty ***due on Licensed Products.***

(iv) From and after the date of initiation throughout the term, LICENSEE shall make a one time payment of [***X dollars]*** upon achieving **[$xx]** in accumulated worldwide sales of the Licensed Products.

(v) From and after the date of initiation throughout the term, LICENSEE shall make a one time payment of X dollars upon successful completion and compliance/approval of ***any regulatory milestone of U.S. Food and Drug Administration (FDA) or any other regulatory Agency as herein detailed: 1, 2, and 3 etc]***.

(vi) LICENSEE will reimburse LICENSOR **[$x] for past costs and/or will pay [*y%]* of all future]** patent prosecution Costs, *if a patent exists*. *If no IP, delete (vi)*

(b) All royalties shall be due and payable within forty-five (45) days of the end of each calendar year.

(c) 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.

(d) LICENSOR will notify LICENSEE in written and/or electronic communication of Department of the Army and USAMRMC control numbers. Checks must be made payable to "DFAS COLUMBUS." On a statement accompanying the check, it shall be noted that the payment is for royalties or licensing fees, and United States Department of Army log number(s) MUST be listed and specifically referenced. In the case where payments of License Fees are made on more than one licensed patent, patent application, invention, technology, or Licensed Product, LICENSEE shall submit an estimated allocation of payments amongst the relevant licensed patents, patent applications, inventions, technologies, or Licensed Products. All checks for payments under this Agreement should be mailed to the below address with a copy to LICENSOR's representative at the address on the signature page.

(e) Address to send payments:

DFAS-CO/JDCBB
PO Box 183133
Columbus, OH 43218-3133

If using Fed-Ex, use this address:

DFAS-CO/JDCBB
3990 E BROAD ST BLDG 21
Columbus, OH 43213-1152

(f) 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.

(g) Additional royalties may be assessed by LICENSOR on any payment that is overdue at the rate of twelve percent (12%) per annum. This twelve percent (12%) per annum rate may be applied retroactively from the original due date until the date of receipt by LICENSOR of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent LICENSOR from exercising any other rights it may have as a consequence of the lateness of any payment.

5. (Upon receipt and verification by LICENSOR of the execution fee and/or other payments agreed to by the parties,) delete if no payment involved) LICENSOR agrees to provide LICENSEE with the Materials and/or Methods, as available, and to replace these Materials and/or Methods, as available, at reasonable cost, in the event of their unintentional destruction.

6. LICENSEE agrees to make written Annual Progress Reports to LICENSOR within forty-five (45) days of December 31for each calendar year, detailing its efforts, and the efforts of all Affiliate(s), to bring the inventions licensed under this Agreement to the point of practical application, together with any additional information requested by LICENSOR or as contemplated and required under the development plan. The Annual Progress Reports and any additional information shall contain reasonably sufficient information to substantiate that LICENSEE is in full compliance with the terms of the Agreement and that the development plan is being executed. No such Annual Progress Reports shall be required with respect to any particular Licensed Product after notification of the first commercial sale of such Licensed Product, unless otherwise requested by LICENSOR. LICENSEE shall submit each Annual Progress Report to LICENSOR at the mailing address for Agreement notices indicated on the signature page.

7. Concurrently with each payment of amounts due and owing LICENSOR under this Agreement, LICENSEE shall also submit a true, accurate and complete written Royalty Reports setting forth for the proceeding six-month reporting period (6), (a) the quantity of Licensed Products made, used, sold or otherwise disposed of by LICENSEE and its Affiliate(s), (b) the gross and Net Sales calculations thereof, and (c) a true, accurate and complete calculation of the amounts due to LICENSOR under this Agreement for each such period. If no License Fees or other payments are due LICENSOR for any reporting period, the Royalty Reports shall so state.

8. This Agreement shall become effective on the **[Execution Date/Effective Date]** and shall expire ***[x]*** years from this effective date, unless previously terminated under one of the other terms of this Agreement. ***[Use patent terminology if patented i.e. life of patent etc.]***

9. As part of LICENSEE's performance under this Agreement, LICENSEE agrees to make the Licensed Products available to the public within ***[x number of months negotiated]***.

10. LICENSEE agrees to retain control over the Materials and/or Methods and the Licensed Products, and not to distribute them to third parties without the prior written consent of LICENSOR except as provided in Paragraph 3.

11. This Agreement does not preclude LICENSOR from distributing the Materials and/or Methods or the Licensed Products to third parties for research or commercial purposes.

12. By this Agreement, LICENSOR grants no patent rights expressly or by implication to any anticipated or pending LICENSOR patent applications or issued patents or new Materials and/or Methods. With the agreement of both parties, this Agreement may be amended to include new or improved Materials and/or Methods. Upon such amendment, the term of this Agreement will be extended by a period to be determined by mutual consent.

13. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS AND/ OR METHODS PROVIDED TO LICENSEE UNDER THIS AGREEMENT, OR THAT THE MATERIALS AND/ OR METHODS OR THE LICENSED PRODUCTS MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. LICENSEE ACCEPTS LICENSE RIGHTS TO THE MATERIALS AND/OR METHODS AND THE LICENSED PRODUCTS “AS IS,” AND LICENSOR DOES NOT OFFER ANY GUARANTEE OF ANY KIND.

14. 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 and/or Methods or the Licensed Products. LICENSEE further agrees that it shall not by its action bring the United States Government into any lawsuit involving the Materials and/or Methods or the Licensed Products.

15. LICENSEE agrees in its use of the supplied Materials and/or Methods or the Licensed Products to comply with all applicable statutes, regulations, and guidelines. LICENSEE agrees not to use the Materials and/or Methods or the Licensed Products and/or Methods for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46 and approval by LICENSOR.

16. LICENSEE may terminate this Agreement upon sixty (60) days written notice to LICENSOR, LICENSOR may terminate this Agreement if LICENSEE is in default in the performance of any material obligation under this Agreement if, and if the default has not been remedied within ninety (90) days after the date of written notice by LICENSOR of the default.

17. Upon termination or expiration of this Agreement, LICENSEE agrees to return all Materials and/or Methods and the Licensed Products to LICENSOR, or provide LICENSOR with written certification of their destruction.

18. Within sixty (60) days of termination or expiration of this Agreement, LICENSEE agrees to submit a final report to LICENSOR, and to submit to LICENSOR payment of any royalties due. LICENSEE agrees to keep records showing the gross sales, Net Sales or other disposition of Licensed Products sold or otherwise disposed of under the license appropriate to determine the amount of fees and other payments due USAMRMC hereunder. Such records, including, without limitation, those of its Affiliates and Sublicensees, shall be retained for a period of five (5) years following the end of the calendar year to which such records pertain, and shall be treated and maintained as Confidential Information of LICENSEE. Such records should be in sufficient detail and clearly organized to enable the fees and any other amounts payable hereunder by LICENSEE to be determined, and LICENSEE further agrees to afford USAMRMC or its designee(s) or agent(s) access to examine any and all relevant books and records of LICENSEE and, where appropriate, its Affiliate(s) and sublicensees, as may be necessary to make such determination. Upon thirty (30) days prior written notice, LICENSEE shall make such records available for examination during normal business hours for the sole purpose of verifying the accuracy of LICENSEE's payments and compliance with this Agreement for any period within the most recently completed five (5) calendar years during the term of this Agreement and for five (5) years after the expiration or termination of this Agreement. If an auditor or certified public accountant is appointed by USAMRMC to conduct such an examination, USAMRMC shall, at LICENSEE's sole cost and expense, review and approve any reasonable request that its designee or agent execute an agreement not to otherwise disclose confidential or proprietary information. LICENSEE shall also assume and pay any and all audit expenses and costs incurred in the event any underpayment is reported which equals or exceeds five percent (5%)of the License Fees or other payments due USAMRMC hereunder. The parties agree to adhere to the rules and procedures established under the Administrative Dispute Resolution Act (5 U.S.C. Section 571, as amended) to resolve any dispute arising under this Section.

19. LICENSEE is encouraged to publish the results of its research projects using the Materials and/or Methods or the Licensed Products. In all oral presentations or written publications concerning the Materials and/or Methods or the Licensed Products, LICENSEE shall acknowledge the contributions of LICENSOR and the agency supplying the Materials and/or Methods, unless requested otherwise by LICENSOR.

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. LICENSEE agrees to be subject to the jurisdiction of U.S. courts.

21. This Agreement constitutes the entire understanding of LICENSOR and LICENSEE and supersedes all prior agreements and understandings with respect to the Materials and/or Methods or the Licensed Products.

22. 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.

23. Paragraph 12, 13, 14, 15, and 20 of this Agreement shall survive termination or expiration of this Agreement.

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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 ***[Laboratory Name]***:

_____ Date:_____
Director Name

Printed Name:

Title:

Mailing Address of LICENSOR's Representative for all Notices and Copies of payments sent to DFAS:

Office of Research and Technology Applications
Staff Judge Advocate (MCMR-JA)
504 Scott Street
Fort Detrick, MD 21702-5012

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.):

For: ***[Company Name]***

_____ Date:_____
Signature of Authorized Official

Title:

Mailing Address:

_____

Any false or misleading statements made, presented, or submitted to the United States 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).