

PUBLIC HEALTH SERVICE

NON-EXCLUSIVE PATENT LICENSE AGREEMENT FOR INTERNAL RESEARCH USE

This **Agreement** is based on the model Non-Exclusive Patent Internal Use 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.: _____

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NIH Patent License Agreement — **Internal Use Only** Nonexclusive
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For **IC**'s internal use only:

License Number:

License Application Number:

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention):

Additional Remarks:

Public Benefit(s):

This Patent License Agreement, hereinafter referred to as the “**Agreement**”, consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Licensed Products, Processes, Territory, Field of Use and Termination), Appendix C (Royalties), Appendix D (Shipping Information) and Appendix E (Royalty Payment Options).

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The **IC** and the **Licensee** agree as follows:

1. BACKGROUND

- 1.1 In the course of conducting biomedical and behavioral research, the **IC** investigators made inventions that may have commercial applicability.
- 1.2 By assignment of rights from the **IC** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by the **IC**.
- 1.3 The Secretary of **HHS** has delegated to the **IC** the authority to enter into this **Agreement** for the licensing of rights to these inventions under [35 U.S.C. §§200-212](#), the [Federal Technology Transfer Act of 1986](#), [15 U.S.C. §3710a](#), and the regulations governing the licensing of Government-owned inventions, [37 C.F.R. Part 404](#).
- 1.4 The **IC** desires to transfer these inventions to the private sector through commercial research licenses to facilitate the commercial development of products and processes for public use and benefit.
- 1.5 The **Licensee** desires to acquire the rights to use certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

- 2.1 “**Affiliate(s)**” means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.
- 2.2 “**Government**” means the government of the United States of America.
- 2.3 “**Licensed Patent Rights**” shall mean:
 - (a) U.S. patent applications and patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;
 - (b) to the extent that the following contain one or more claims directed to the invention or inventions claimed in 2.3(a):
 - (i) continuations-in-part of 2.3(a);
 - (ii) all divisions and continuations of these continuations-in-part;
 - (iii) all patents issuing from these continuations-in-part, divisions, and continuations; and

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- (iv) any reissues, reexaminations, and extensions of these patents;
 - (c) to the extent that the following contain one or more claims directed to the invention or inventions claimed in 2.3(a): all counterpart foreign applications and patents to 2.3(a) and 2.3(b), including those listed in Appendix A; and
 - (d) **Licensed Patent Rights** shall *not* include 2.3(b) or 2.3(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter of a claim in 2.3(a).
- 2.4 “**Licensed Products**” means tangible materials, identified in Appendix B, which, in the course of manufacture, use, sale, or importation would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.
- 2.5 “**Licensed Processes**” means processes, identified in Appendix B, which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.
- 2.6 “**Licensed Territory**” means the geographical area identified in Appendix B.
- 2.7 “**Licensed Fields of Use**” means the field of use identified in Appendix B.

3. GRANT OF RIGHTS

- 3.1 The **IC** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and to use, but not to sell **Licensed Products** and **Licensed Processes** in the **Licensed Fields of Use**.
- 3.2 The **Licensee** has no right to sublicense.
- 3.3 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **IC** other than the **Licensed Patent Rights** regardless of whether such patents are dominant or subordinate to the **Licensed Patent Rights**.
- 3.4 The **IC** acknowledges that information relating to the **Licensed Patent Rights** may be of assistance to the **Licensee** in its research efforts. Accordingly, the **IC** shall consider reasonable requests by the **Licensee** for access to the inventors of the **Licensed Patent Rights**.

4. ROYALTIES

- 4.1 The **Licensee** agrees to pay the **IC** a non-creditable, nonrefundable license issue royalty as set forth in Appendix C.
- 4.2 The **Licensee** agrees to pay the **IC** a nonrefundable annual royalty as set forth in Appendix C.

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- 4.3 All royalties due under this **Agreement** shall be paid in U.S. dollars, net of all non-U.S. taxes, and payment options are listed in Appendix E. 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.
- 4.4 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. PERFORMANCE

- 5.1 Upon receipt and verification of the royalties due under Paragraphs 4.1 and 4.2, the **IC** agrees, if **Licensed Products** are available to the **IC**, to provide the **Licensee**, at the **Licensee's** expense, with samples of the **Licensed Products** to the individual and address listed in Appendix D and, at reasonable cost to the **Licensee**, to replace them in the event of their unintentional destruction. The **Licensee** agrees to retain control over the **Licensed Products** and shall not distribute or release them to others without the prior written consent of the **IC**.
- 5.2 The **Licensee** shall expend reasonable efforts and resources to carry out the research development plan submitted with the **Licensee's** application for a license and shall begin research within six (6) months of the effective date of this **Agreement**.
- 5.3 The **Licensee** agrees in its use of any **Licensed Products** provided by the **IC** to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use 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 **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying the **IC**, in writing, of this 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 this research or trials.
- 5.4 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](#).

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6. NEGATION OF WARRANTIES AND INDEMNIFICATION

- 6.1 The **IC** offers no warranties other than those expressly specified in Article 1.
- 6.2 The **IC** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.
- 6.3 **THE IC MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE LICENSED PATENT RIGHTS OR OF ANY LICENSED PRODUCTS PROVIDED TO THE LICENSEE UNDER PARAGRAPH 5.1.**
- 6.4 The **IC** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.
- 6.5 The **Licensee** shall indemnify and hold the **IC**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:
- (a) the use by the **Licensee**, its directors, employees, or third parties of any **Licensed Patent Rights**, or
 - (b) the design, manufacture, distribution, or use of any **Licensed Products** or materials provided under Paragraph 5.1, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.
- 6.6 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

7. TERM, TERMINATION AND MODIFICATION OF RIGHTS

- 7.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 8.8 are not fulfilled, and shall expire at the time specified in Appendix B, unless previously terminated under the terms of this Article 7.
- 7.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 7.3 and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, the **IC** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the [Federal Debt Collection Act](#).
- 7.3 The **IC** shall specifically have the right to terminate this **Agreement** by written notice if the **Licensee**:

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- (a) has not demonstrated that it is executing the research plan submitted with its application for a license or that it has not taken or cannot be expected to take, within a reasonable time, effective steps to achieve the practical application of the **Licensed Patent Rights** as contemplated by this **Agreement**; or
 - (b) has willfully made a false statement of or willfully omitted a material fact in its application for a license or in any report required by this **Agreement**.
- 7.4 The **IC** reserves the right according to [35 U.S.C. §209\(d\)\(3\)](#) to terminate this **Agreement** if it is determined that this action is necessary to meet the requirements for public use specified by Federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.
- 7.5 The **Licensee** shall have a unilateral right to terminate this **Agreement** by giving the **IC** sixty (60) days written notice to that effect.
- 7.6 Within thirty (30) days of receipt of written notice of the **IC's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of [37 C.F.R. §404.11](#), appeal the decision by written submission to the designated **IC** official. The decision of the designated **IC** official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be accessible.
- 7.7 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.
- 7.8 Within ninety (90) days of expiration, termination or term extension of this **Agreement** under this Article 7, a final report shall be submitted by the **Licensee**. The **Licensee** shall send the report to the **IC** at the Mailing Address for **Agreement** notices indicated on the Signature Page.
- (a) The report shall include, but not be limited to, progress on the research and development involving the **Licensed Patent Rights**, the **Licensed Products** or the **Licensed Processes**.
 - (b) Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty) due to the **IC** shall become immediately due and payable upon termination or expiration. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to the **IC** or provide the **IC** with written certification of the destruction thereof.
 - (c) 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 7.8(a);

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

7.9 Paragraphs 4.3, 4.4, 5.4, 6.1-6.5, 7.6, 7.8 and 7.9 of this **Agreement** shall survive termination of this **Agreement**.

8. GENERAL PROVISIONS

- 8.1 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.
- 8.2 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 determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
- 8.3 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.
- 8.4 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by such other party, and shall be effective as of the date of the postmark of such notice.
- 8.5 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Licensee's Affiliate(s)** without the prior written consent of the **IC**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable.
- 8.6 The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the [Export Administration Act of 1979](#) and [Arms Export Control Act](#)) controlling the export of technical data, computer software, laboratory prototypes, biological materials and other commodities. The transfer of these items may require a license from the appropriate agency of the **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of the agency. The **IC** neither represents that a license is or is not required or that, if required, it shall be issued.
- 8.7 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modification or termination decisions provided for in Article 7. The **Licensee** agrees first to appeal any such unsettled claims or controversies to the designated **IC** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available.

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- 8.8 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

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**NIH NON-EXCLUSIVE PATENT LICENSE AGREEMENT
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FOR IC:

by: _____ **DRAFT** _____
Name _____ Date _____
Title _____
Office _____
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 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.):

Licensee

by: _____ **DRAFT** _____
Signature of Authorized Official _____ Date _____

Printed Name

Title

I. Official and Mailing Address for **Agreement** notices:

Name

Title

Mailing Address

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Email Address: _____

Phone: _____

Fax: _____

II. Official and Mailing Address for Financial notices (**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) or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

I.

II.

III.

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**APPENDIX B – LICENSED PRODUCTS, PROCESSES, TERRITORY, FIELD OF USE AND
TERMINATION**

I. Licensed Products:

(a)

II. Licensed Processes:

(a)

III. Licensed Territory:

(a)

IV. Licensed Fields of Use:

(a)

V. Termination:

(a) This **Agreement** shall expire _____ (X) years from the effective date as defined in Paragraph 7.1 unless previously terminated under Article 7.

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APPENDIX C – ROYALTIES

Royalties:

- I. The **Licensee** agrees to pay to the **IC** a noncreditable, nonrefundable license issue royalty in the amount of _____ dollars (\$X) within sixty (60) days from the effective date of this **Agreement**.
- II. The **Licensee** agrees to pay to the **IC** a nonrefundable annual royalty in the amount of _____ dollars (\$X) as follows:
 - (a) The first annual royalty 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; and
 - (a) Subsequent annual royalty payments are due and payable on January 1 of each calendar year.

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APPENDIX D – 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 E – ROYALTY PAYMENT OPTIONS

New Payment Options Effective March 2018

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 \$24,999. 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:

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	<i>(enter payment amount)</i>
{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)	<i>(enter 12 digit gateway account #)</i> 875080031006
{4200}	Beneficiary Name	<i>(enter agency name associated with the Beneficiary Identifier)</i> DHHS / NIH (75080031)
{5000}	Originator	<i>(enter the name of the originator of the payment)</i> COMPANY NAME
{6000}	Originator to Beneficiary Information – Line 1	<i>(enter information to identify the purpose of the payment)</i> ROYALTY
{6000}	Originator to Beneficiary Information – Line 2	<i>(enter information to identify the purpose of the payment)</i> LICENSE NUMBER
{6000}	Originator to Beneficiary Information – Line 3	<i>(enter information to identify the purpose of the payment)</i> INVOICE NUMBER

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Fedwire Field Tag	Fedwire Field Name	Required Information
{6000}	Originator to Beneficiary Information – Line 4	<i>(enter information to identify the purpose of the payment)</i>
Notes: *The financial institution address for Treasury’s routing number is <u>33 Liberty Street, New York, NY 10045</u> .		

Agency Contacts: Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

Drawn on a **foreign 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}	Type/Subtype	1000
{2000}	Amount	<i>(enter payment amount)</i>
{3100}	Sender Bank ABA routing number	<i>(enter the US correspondent bank’s ABA routing number)</i>
{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)**	<i>(enter 12 digit gateway account #)</i> 875080031006
{4200}	Beneficiary Name	<i>(enter agency name associated with the Beneficiary Identifier)</i> DHHS / NIH (75080031)
{5000}	Originator	<i>(enter the name of the originator of the payment)</i> COMPANY’S NAME
{6000}	Originator to Beneficiary Information – Line 1	<i>(enter information to identify the purpose of the payment)</i> ROYALTY
{6000}	Originator to Beneficiary Information – Line 2	<i>(enter information to identify the purpose of the payment)</i> LICENSE NUMBER
{6000}	Originator to Beneficiary Information – Line 3	<i>(enter information to identify the purpose of the payment)</i> INVOICE NUMBER
{6000}	Originator to Beneficiary Information – Line 4	<i>(enter information to identify the purpose of the payment)</i>
Notes: *The financial institution address for Treasury’s routing number is <u>33 Liberty Street, New York, NY 10045</u> . **Anything other than the 12 digit gateway account # will cause the Fedwire to be returned – SWIFT CODE: FRNYUS33		

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Agency Contacts:

Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

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
P.O. Box 979071
St. Louis, MO 63197-9000

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

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