This Agreement is based on the model Interinstitutional Institution Lead 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 “Institution”,

having offices at [Insert Company’s address],

created and operating under the laws of [Insert State of Incorporation].
1. BACKGROUND

1.1 In the course of fundamental research programs at the IC, under a HHS funding agreement (Grant/Contract No. ___________), _________________(Inventor(s)) made or reduced to practice certain inventions which are included within the Patent Rights, as defined in Paragraph 2.2.

1.2 It is the mutual desire of the Institution and the IC that their respective undivided interests in the Patent Rights be administered in a manner to ensure the rapid commercialization of the Patent Rights and to make their benefits widely available to the public. Therefore, in accordance with 35 U.S.C. §202(e) and 37 C.F.R. §401.10, the IC is granting an exclusive license to IC’s rights in the Patent Rights to the Institution under the conditions set forth herein.

2. DEFINITIONS

2.1 “Government” means the government of the United States of America.

2.2 “Patent Rights” means:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents as follows: U.S. Patent Application Serial No./U.S. Provisional Patent Application Serial No. _____/______,______, filed __________, entitled ____________________, and any patent application(s) claiming the benefit of priority thereof including all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all these patents to the extent that at least one Inventor from the Institution is an Inventor thereon;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.2(a) and to the extent that at least one Inventor from the Institution is an Inventor:

(i) continuations-in-part of 2.2(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.2(a); and

(v) any reissues, reexaminations, and extensions of all these patents; and

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.2(a) and to the extent that at least one Inventor from the Institution is an Inventor: all counterpart foreign and U.S. patent applications and patents to 2.2(a) and 2.2(b); and
(d) **Patent Rights** shall *not* include 2.2(b) or 2.2(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.2(a).

2.3 “Net Revenues” means all consideration received by the **Institution** from the licensing of the **Patent Rights** pursuant to this **Agreement** less (a) **Expenses** and then (b) ______ percent (X%) of the remaining consideration for administrative overhead. In the event that a license is executed by **Institution** with a third party wherein the **Patent Rights** are licensed together with other technologies not falling under the definition of the **Patent Rights**, all consideration received by the **Institution** from the licensing of the **Patent Rights** pursuant to this **Agreement** through the third-party executed license shall correspond to the **Patent Rights’** percentage contribution to the total amount received for all licensed technologies as determined by the **Institution**.

2.4 “**Expenses**” means all reasonable and actual out-of-pocket costs, excluding those reimbursed by a third party, paid by the **Institution** for the preparation, filing, prosecution, and licensing of United States and foreign patent applications, extraordinary expenses as provided in Paragraph 4.6, and the maintenance of the resulting patents or patent applications, exclusive of any salaries, administrative, or other indirect costs.

2.5 “**Research License**” means a nontransferable, nonexclusive license to make and to use any tangible embodiment of the **Patent Rights** and to practice any process(es) included within the **Patent Rights** for purposes of internal research and not for purposes of commercial manufacture or distribution or in lieu of purchase.

2.6 “**Practical Application**” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or by regulations of the **Government**, available to the public on reasonable terms.

3. **GRANT AND RESERVATION OF RIGHTS**

3.1 The **IC** hereby grants and the **Institution** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license, including the right to sublicense, under the **Patent Rights** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any tangible embodiment of the **Patent Rights** and to practice and have practiced any process included within the **Patent Rights**.

3.2 The **Government** shall have the irrevocable, royalty-free, paid-up right to practice and have practiced the **Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory. Any license granted by the **Institution** under the terms of this **Agreement** shall be subject to this right of the **Government**.

3.3 The **IC** reserves the right to require the **Institution**, or its licensees, to grant sublicenses to responsible applicants, on terms that are reasonable under the circumstances when necessary to fulfill health or safety needs or when necessary to meet requirements for public use specified by Federal regulations.

3.4 In addition to the reserved right of Paragraph 3.3, the **IC** reserves the right to require the **Institution** to grant **Research Licenses** on reasonable terms and conditions. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility.
4. PATENT PROSECUTION AND PROTECTION

4.1 The Institution shall file, prosecute, and maintain patent application(s) relating to the Patent Rights and shall promptly provide to the IC all serial numbers and filing dates, together with copies of all these applications, including copies of all Patent Office actions, responses, and all other Patent Office communications. In addition, the Institution, shall file with Patent Offices, a Power of Attorney, that names both the Institution and the IC. This Power of Attorney shall be filed with every Patent Office involved in prosecuting all patent applications pertaining to Patent Rights. The Institution shall consult with the IC, when so requested, prior to communicating with any Patent Office with respect to the Patent Rights.

4.2 The Institution shall make an election with respect to foreign filing, upon consultation with the IC, including which countries foreign filing shall be done prior to the election, within eight (8) months of any United States filing. If any foreign patent applications are filed, the Institution shall promptly provide to the IC all serial numbers and filing dates. The Institution also shall provide the IC copies of foreign patent applications and Patent Office actions. The Institution shall consult with the IC, when so requested, prior to communicating with any Patent Office with respect to the Patent Rights.

4.3 The Institution shall promptly record Assignments of domestic Patent Rights in the United States Patent and Trademark Office and shall promptly provide the IC with the original of each recorded Assignment with respect to the IC.

4.4 Notwithstanding any other provision of this Agreement, the Institution shall not abandon the prosecution of any patent application, including provisional patent applications (except for purposes of filing continuation application(s)) or the maintenance of any patent contemplated by this Agreement, without prior written notice to the IC. Upon receiving the written notice, the IC may, at its sole option, take over the prosecution of any patent application, or the maintenance of any patent.

4.5 The Institution shall promptly provide the IC with copies of all issued patents under this Agreement.

4.6 In the event that the Institution anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this Agreement, including, without limitation, interferences, reexaminations, reissues and oppositions, the Institution shall provide the IC with all relevant information, and these extraordinary expenditures shall be included as Expenses only upon written agreement of the IC. The Institution and the IC shall agree on a mutually acceptable course of action prior to incurring these expenditures.

5. LICENSING

5.1 The Institution shall diligently seek licensees for the commercial development of the Patent Rights and shall administer the Patent Rights for the mutual benefit of the parties and in the public interest. The Institution shall ensure that any license granted for the Patent Rights is subject to the provisions of 37 C.F.R. Part 401 and the rights retained by the Government under this Agreement, including the requirement for substantial manufacture in the United States as stated in Paragraph 11.1.

5.2 The Institution shall not issue any royalty-free or paid-up licenses or assign Patent Rights to any third party, notwithstanding any other provision of this Agreement, without the prior written consent of the IC.

5.3 The Institution shall consult with the IC in the negotiation of any exclusive or partially-exclusive licenses, notwithstanding any other provision of this Agreement, and shall not grant these licenses without the prior review, opportunity for comment, and written approval of the IC.
5.4 Before licensing of the Patent Rights or any part thereof by the Institution, the Institution shall first notify and confer with the IC regarding any research funding related to the Patent Rights so as to determine the IC’s interest in participating in any funded collaborative research project.

5.5 The Institution shall promptly provide the IC with complete copies of all licenses and sublicenses granted for the Patent Rights.

5.6 Institution agrees that its licensees shall 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 licensed processes, as covered by the Patent Rights, or their packaging for educational and display purposes only.

6. ROYALTIES AND EXPENSES

6.1 The Institution shall distribute Net Revenues to the IC concurrently with distributions it makes under the Institution’s patent policy, but in any case not later than April 1 for the preceding calendar year, on the following basis: (a) ______ percent (X%) of the Net Revenues as a royalty to the Institution and (b) ______ percent (X%) of the Net Revenues as a royalty to the IC.

6.2 All payments to the IC, required under this Agreement, shall be in U.S. dollars and payment options are listed in Appendix A.

(a) 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 Institution; and

(b) 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.

6.3 The Institution shall submit to the IC annual statements of itemized Expenses as defined in Paragraph 2.4 and shall deduct the Expenses as provided for in Paragraph 2.3, except where IC has identified discrepancies in billing by the Institution, in which case, deduction of the contested item(s), as a part of the Expenses as provided for in Paragraph 2.4, shall be delayed pending resolution thereof.

6.4 In no event shall the IC be obligated to bear any costs for Expenses under this Agreement.

6.5 Each party shall be solely responsible for calculating and distributing to its respective Inventor(s) of the Patent Rights any share of Net Revenues in accordance with its respective patent policy, royalty policy, or Federal law during the term of this Agreement.

7. RECORDS AND REPORTS

7.1 The Institution shall keep complete, true, and accurate accounts of all Expenses and of all Net Revenues received by it from each licensee of the Patent Rights and shall permit the IC or the IC’s designated agent to examine its books and records in order to verify the payments due or owed under this Agreement.
7.2 Upon request by the IC, the Institution shall submit to the IC an annual report, not later than April 1 of each year, setting forth the status of all patent prosecution, commercial development, and licensing activity relating to the Patent Rights for the preceding calendar year.

8. **PATENT INFRINGEMENT**

8.1 In the event the IC or the Institution, including its licensees, shall learn of the substantial infringement of any patent subject to this Agreement, the party who learns of the infringement shall promptly notify the other party in writing and shall provide the other party with all available evidence of the infringement. The Institution and its licensees, in cooperation with the IC, shall use their best efforts to eliminate the infringement without litigation. If the efforts of the parties are not successful in eliminating the infringement within ninety (90) days after the infringer has been formally notified of the infringement by the Institution, the Institution shall have the right, after consulting with the IC, to commence suit on its own account. The IC may join the Institution’s suit or commence its own suit.

8.2 The Institution may permit its licensees to bring suit on their own account, but only if the IC and the Institution elect not to commence separately or join each other in any suit, other than as nominal party plaintiff, either by formal notice or by failure to act within the ninety (90) day period set forth in Paragraph 8.1. The IC shall retain the right to join any licensee's suit.

8.3 Neither a licensee nor the Institution shall take action to compel the IC either to initiate or to join in any suit for patent infringement. Should the Government be made a party to any suit by motion or any other action of a licensee or the Institution, the licensee or the Institution shall reimburse the Government for any costs, expenses, or fees which the Government incurs as a result of the motion or other action, including any and all costs incurred by the IC in opposing any joinder action.

8.4 Legal action or suits to eliminate infringement or recover damages pursuant to Paragraph 8.1 shall be at the full expense of the party by whom suit is brought. All damages recovered thereby shall first be used to reimburse each party for its expenses relating to the legal action, and the remainder of the damages shall be considered Net Revenues.

8.5 Each party agrees to cooperate with the other in litigation proceedings. The IC may be represented, at its expense, by counsel of its choice in any suit.

9. **GOVERNING LAWS, SETTLING DISPUTES**

9.1 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 Institution agrees to be subject to the jurisdiction of U.S. courts.

9.2 Any controversy or any disputed claim by either party against the other arising under or related to this Agreement shall be submitted jointly to the Institution’s President or designee and to the IC official or designee for resolution. The Institution and the IC shall be free after written decisions are issued by those officials to pursue all administrative or judicial remedies which may be available.

10. **TERM AND TERMINATION**

10.1 This Agreement is effective when signed by all parties, unless the provisions of Paragraph 11.9 are not fulfilled, and shall extend to the expiration of the last to expire of the patents included within the Patent Rights unless otherwise terminated by operation of law or by acts of the parties in accordance with the terms of this Agreement.
10.2 The **Institution** may terminate this **Agreement** upon at least sixty (60) days written notice to the **IC**, but in any event not less than sixty (60) days prior to the date on which any pending Patent Office actions need be taken to preserve patent rights for the benefit of the parties hereto.

10.3 In the event the **Institution** has made no commitments to any third party for exclusive license rights relating to the **Patent Rights**, the **IC** may terminate this **Agreement** for any reason upon thirty (30) days written notice to the **Institution**. During the term of any option agreement or license agreement to any third party for exclusive license rights relating to the **Patent Rights** between the **Institution** and an optionee or licensee, the **IC** may terminate this **Agreement** when:

(a) it is determined by the **IC**'s:

(i) The **Institution** or its licensee has not taken and is not expected to take effective steps to achieve **Practical Application** of the **Patent Rights**;

(ii) Termination is necessary to alleviate health or safety needs which are not reasonably satisfied by the **Institution** or its licensee;

(iii) Termination is necessary to meet requirements for public use specified by Federal law or regulations and these requirements are not reasonably satisfied by the **Institution** or its licensees; or

(iv) Termination is necessary because the requirements of 35 U.S.C. §204 have not been satisfied or waived or because a licensee of the exclusive right to use or sell the **Patent Rights** in the United States is in breach of its agreement obtained pursuant to Section 204;

(b) the **Institution** or affected third party has been notified of this determination and has been given at least thirty (30) days to provide a response to this determination, and

(c) the **Institution**'s or affected third party's response to the determination of 10.3(a)(i)-(iv) is determined to be unsatisfactory by the Office of Technology Transfer.

10.4 The **IC** may terminate this **Agreement** in whole or in part if:

(a) the **Institution** fails to make any payment or periodic reports required by this **Agreement**;

(b) the **Institution** has willfully made a false statement of, or willfully omitted, a material fact in the negotiation of the **Agreement** or in any report required by the **Agreement**;

(c) the **Institution** has committed a substantial breach of a covenant or duty contained in this **Agreement**; or
the IC and the **Institution** are involved in a dispute under this **Agreement** which cannot be resolved under the procedures specified in Paragraph 9.2. If the **Agreement** is terminated under this Paragraph 10.4, the IC agrees to provide affected licensees an opportunity to license the **Patent Rights** subject to the restrictions of **37 C.F.R. Part 404**, under terms as may have been agreed to by the **Institution**.

11. **GENERAL**

11.1 The **Institution** agrees that, for use and sale of the **Patent Rights** in the United States, any products embodying the **Patent Rights**, or produced through use of the **Patent Rights**, shall be manufactured substantially in the United States unless a waiver is granted by the IC.

11.2 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to the other address as may be designated in writing by such other party. **Agreement** notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

11.3 This **Agreement** shall not be construed to confer on any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this **Agreement** shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

11.4 It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.

11.5 This **Agreement** is binding upon and shall inure to the benefit of the parties hereto and their successors or assigns, but this **Agreement** may not be assigned by either party without the prior written consent of the other party.

11.6 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the IC other than the **Patent Rights** regardless of whether such patents are dominant or subordinate to the **Patent Rights**.

11.7 Any modification to this **Agreement** must be in writing and agreed to by both parties.

11.8 It is understood and agreed by the **Institution** and the IC that this **Agreement** constitutes the entire agreement between the parties, and that all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, shall be abrogated, canceled, and are null and void and of no effect.

11.9 The terms and conditions of this **Agreement** shall, at the IC’s sole option, be considered by the IC to be withdrawn from **Institution’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 **Institution** and a fully executed original is received by the IC within sixty (60) days from the date of the IC’s signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**
NIH INTERINSTITUTIONAL AGREEMENT – INSTITUTION

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their respective duly authorized officers, who have affixed their signatures hereunto, on the day and year hereinafter written. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For the IC:

DRAFT

Name
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
6701 Rockledge Drive, Suite 700 MS 7788
Bethesda, Maryland 20892 U.S.A.

E-mail: LicenseNotices_Reports@mail.nih.gov

For the Institution:

Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the Institution made or referred to in this Agreement are truthful and accurate.

DRAFT

Signature of Authorized Official

Date

Printed Name

Title

Official and Mailing Address for Agreement notices:

Name

Title

Mailing Address:

A-XXX-201X

CONFIDENTIAL
NIH Interinstitutional Agreement—Institution Lead
Model 10-2015 (updated 2-29-16)
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 – 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](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/startJ28680443](https://www.pay.gov/public/form/startJ28680443). 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**.

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<th>Fedwire Field Name</th>
<th>Required Information</th>
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<td>Business Function Code</td>
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Notes:
*The financial institution address for Treasury’s routing number is 33 Liberty Street, New York, NY 10045.*
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.

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<tr>
<th>Fedwire Field Tag</th>
<th>Fedwire Field Name</th>
<th>Required Information</th>
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<td>Amount</td>
<td>(enter payment amount)</td>
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<tr>
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<td>Sender Bank ABA routing number</td>
<td>(enter the US correspondent bank’s ABA routing number)</td>
</tr>
<tr>
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<td>{3400}</td>
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</tr>
<tr>
<td>{3600}</td>
<td>Business Function Code</td>
<td>CTR (or CTP)</td>
</tr>
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<td>{4200}</td>
<td>Beneficiary Identifier (account number)**</td>
<td>(enter 12 digit gateway account #) 875080031006</td>
</tr>
<tr>
<td>{4200}</td>
<td>Beneficiary Name</td>
<td>(enter agency name associated with the Beneficiary Identifier) DHHS / NIH (75080031)</td>
</tr>
<tr>
<td>{5000}</td>
<td>Originator</td>
<td>(enter the name of the originator of the payment) COMPANY’S NAME</td>
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<tr>
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<td>(enter information to identify the purpose of the payment) ROYALTY</td>
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<td>(enter information to identify the purpose of the payment)</td>
</tr>
</tbody>
</table>

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

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:

A-XXX-201X

CONFIDENTIAL
NIH Interinstitutional Agreement—Institution Lead
Model 10-2015 (updated 2-29-16)
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  
6701 Rockledge Drive, Suite 700 MS 7788  
Bethesda, Maryland 20892 U.S.A.