

# NIH-Moderna-Confidential-Agreements

## *Confidential Disclosure Agreement*

In order to protect confidential information relating to research, development, business plans, and other technology, which may be disclosed between them, the Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health (“NIAID”), and the “Collaborator” identified below (individually, a “Party”; collectively the “Parties”), intending to be legally bound as of the date of the last signature hereto (“Effective Date”), agree that:

1. A Party (“Disclosing Party”) may disclose information to the other (“Receiving Party”) for the purpose of assessing their interest in research collaboration (the “Purpose”). The Disclosing Parties are: **NIAID; Moderna Therapeutics, Inc. and its affiliates,** Proprietary Info (the “Collaborator”).

2. The Parties’ representatives for disclosing or receiving information (if known):

For NIAID: Barney Graham and other employees and contractors of NIAID as needed to fulfill the Purpose.

For Collaborator: Giuseppe Ciaramella,  
Stephane Bancel,  
Lee Cooper, and other employees of the Collaborator as needed to fulfill the Purpose

3. The information disclosed under this Agreement (“Confidential Information”) includes any and all technical, business and financial information, including third party information, relating to the Disclosing Party, including but not limited to: (a) non-public patent applications; Proprietary Info and (c) other proprietary information, ideas, gene sequences, samples, chemical compounds, biological materials, techniques, works of authorship, non-public inventions, know-how and processes related to the current, future, and proposed products and/or services of the Disclosing Party or its partners, and including without limitation, information concerning research, experimental work, development, design details and specifications, engineering, financial information, procurement requirements, purchasing, manufacturing, customer lists, investors, employees, business and contractual relationships, business forecasts, analyst reports, marketing plans and any additional non-public information that the Disclosing Party provides.

The Confidential Information disclosed under this Agreement is described as:

For NIAID: NIAID’s proprietary information and data relating to the development of vaccines for HIV, influenza, Ebola and MERS and development of broadly neutralizing monoclonal antibodies for preventative and therapeutic use.

For Collaborator: Moderna’s proprietary and confidential information related to design and manufacture of a messenger RNA platform and messenger RNA constructs for treatment and prevention of disease.

4. The Receiving Party will not disclose the Confidential Information of the Disclosing Party to any person except its employees, consultants, contractors, directors, or professional advisors or authorized representatives to whom it is necessary to disclose the Confidential Information for the Purpose described above, and any such disclosures shall be under terms at least as restrictive as those specified herein. Any of the persons mentioned above who are given access to the Confidential Information shall be informed of this Agreement. The Receiving Party shall protect the Confidential Information by using the same degree

of care, but no less than a reasonable degree of care, as the Receiving Party uses to protect its own confidential information.

5. The Disclosing Party shall use reasonable efforts to (a) mark Confidential Information in any written document, memorandum, report, correspondence, drawing, or other tangible material, or computer software or program, developed or prepared by the Disclosing Party or any of its representatives as "Confidential" and (b) reduce oral disclosures to writing (this may be by summary email or other electronic communication) marked "Confidential" within thirty (30) days after disclosure. Notwithstanding the above, failure to mark information as "Confidential" will not disqualify that information from constituting "Confidential Information" under this Agreement if a reasonable person would consider such information to be confidential based on the nature of such information and the circumstances of disclosure.

6. Notwithstanding any other provision of this Agreement, Confidential Information shall not include any item of information, data, patent or idea that: (a) is within the public domain prior to the time of the disclosure by the Disclosing Party to the Receiving Party or thereafter becomes within the public domain other than as a result of disclosure by the Receiving Party or any of its representatives in violation of this Agreement; (b) was, on or before the date of disclosure in the possession of the Receiving Party as shown by contemporaneous written record; (c) is acquired by the Receiving Party from a third party not under an obligation of confidentiality; (d) is hereafter independently developed by the Receiving Party, without reference to the information received from the Disclosing Party; or (e) the Disclosing Party expressly authorizes in writing the Receiving Party to disclose.

7. At the request of the Disclosing Party, the Receiving Party agrees to return or certify the destruction of all Confidential Information received from the Disclosing Party except that the Receiving Party may retain in its confidential files one (1) copy of written Confidential Information for record purposes only.

8. If the Receiving Party, or anyone to whom it discloses the Confidential Information in accordance with Paragraph 4, becomes legally required to disclose any of the Confidential Information, the Receiving Party shall provide the Disclosing Party with timely notice and, to the extent practicable, consult with the Disclosing Party prior to any disclosure.

9. This Agreement constitutes the entire understanding between the Parties with respect to the subject matter hereof and merges any and all prior agreements, understandings and representations. The Agreement may not be superseded, amended or modified except by written agreement between the Parties. Any dispute under this Agreement shall be brought in the federal court located in the District of Columbia, and the Parties hereby consent to the personal jurisdiction and exclusive venue of that court. This Agreement is to be made under and shall be construed in accordance with New York and U.S. federal law as applied in the federal court of the District of Columbia. In case of conflict of laws, U.S. federal law as applied in the federal court of the District of Columbia shall prevail. Each Party acknowledges that its breach of this Agreement may cause irreparable damage and hereby agrees that the other Party may be entitled to seek injunctive relief under this Agreement for any actual or threatened breach, as well as such further relief as may be granted by a court of competent jurisdiction. If any provision of this Agreement is found by a proper authority to be unenforceable or invalid, such unenforceability or invalidity will not render this Agreement unenforceable or invalid as a whole, and such provision will be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision within the limits of applicable law or applicable court decisions.

10. This Agreement will control the disclosure of Confidential Information for a disclosure period beginning on the Effective Date and expiring twelve (12) months thereafter, and will otherwise remain in

effect for three (3) years from the Effective Date. Either Party may terminate this Agreement upon thirty (30) days written notice to the other Party, however, each Parties' obligation of maintaining confidentiality will survive termination for three (3) years after the Effective Date.

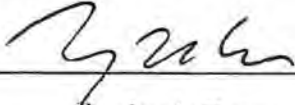
11. This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument. A facsimile, scanned electronic signature or certified electronic signature shall be as effective as an original signature.

**SIGNATURES BEGIN ON NEXT PAGE**

Moderna Therapeutics, Inc.  
320 Bent Street  
Cambridge, MA 02141

Vaccine Research Center, NIAID, NIH  
c/o Technology Transfer & Intellectual Property Office  
Suite 6D, MSC 9804  
5601 Fishers Lane  
Rockville, MD 20852

Authorized Signature:



Name: Benjamin Emerson  
Corporate Counsel

Title: \_\_\_\_\_

Date: 11/6/2015

Authorized Signature:

Carol A. Salata - S

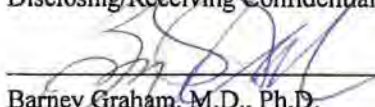
Digitally signed by Carol A. Salata - S  
DN: cn=US, ou=U.S. Government, ou=HHS, ou=NIH,  
ou=People, o=2342.19200500.100.1.1-0010042552,  
c=Carol A. Salata - S  
Date: 2015.11.06 11:05:46 -0500

Carol Salata, Ph.D.  
Senior Technology Transfer Advisor  
Technology Transfer & Intellectual Property Office, NIAID

Date: \_\_\_\_\_

Acknowledged by VRC Representative(s)

Disclosing/Receiving Confidential Information:

  
Barney Graham, M.D., Ph.D.

Date: 9 Nov 2015

**Amendment #01 to the Confidential Disclosure Agreement**

THIS AMENDMENT #01 TO THE CONFIDENTIAL DISCLOSURE AGREEMENT (this "Amendment"), is entered into as of October 28, 2016 (the "Amendment Effective Date"), by and between ModernaTX, Inc. (formerly known as Moderna Therapeutics, Inc.) ("Moderna"), and the Vaccine Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health ("NIAID"). Each of Moderna and NIAID may be referred to herein as a "Party" or together as the "Parties".

**WHEREAS**, Moderna and NIAID are parties to a Confidential Disclosure Agreement dated November 9, 2015 (the "Agreement");

**WHEREAS**, the Agreement expires on November 9, 2016; and

**WHEREAS**, Moderna and NIAID desire to continue the Agreement in accordance with and subject to the terms and conditions therein, as more fully described herein.

**NOW THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which is hereby mutually acknowledged, NIAID and Moderna hereby agree as follows:

1. Definitions. All terms used in this Amendment and not otherwise defined herein shall have the same meanings ascribed to them in the Agreement.

2. Amendments.

(b) Section 3. The Confidential Information of NIAID to be disclosed under the Agreement is hereby amended to include the Zika virus and related vaccines and assays.

(c) Section 10. Section 10 of the Agreement is deleted in its entirety and is replaced with the following:


10. This Agreement will control the disclosure Confidential Information for a disclosure period beginning on the Effective Date and expiring twenty-four (24) months thereafter (i.e. November 9, 2017), and will otherwise remain in effect for four (4) years from the Effective Date. Either Party may terminate this Agreement upon thirty (30) days written notice to the other Party, however, each Parties' obligations of maintaining confidentiality will survive termination for a period of four (4) years after the Effective Date.

3. General Terms. Except with respect to the amendments as set forth in Section 2 above, the terms and conditions of the Agreement shall remain unchanged. This Amendment shall be construed in in accordance with and governed by the same laws that govern the Agreement.

**[Remainder of page intentionally left blank]**

IN WITNESS WHEREOF, NIAID and Moderna each has caused this Amendment to be executed by its duly authorized representative.

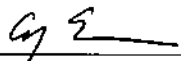
**MODERNATX, INC.**

By:   
(Signature)

Name: Benjamin Enerson  
Corporate Counsel

Title: \_\_\_\_\_

**VACCINE CENTER, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES,  
NATIONAL INSTITUTES OF HEALTH**

By:   
(Signature)

Name: Carol Salata, PhD

Title: Senior Advisor for Technology Transfer, TTPO, NIAID

AMENDMENT NO. 2  
TO  
CONFIDENTIAL DISCLOSURE AGREEMENT

This Amendment No. 2 to Nondisclosure Agreement (NIAID Ref. No. 201-33448) is made as of the 18<sup>th</sup> day of November, 2016 by and between ModernaTX, Inc. (“Moderna”) and the Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health (“NIAID”). Each of Moderna and NIAID may be referred to herein as a “Party” or together as “Parties.”

WHEREAS, Moderna and NIAID entered into a Confidential Disclosure Agreement, dated November 9, 2015 (the “Agreement”) and amended once effective on October 28, 2016; and

WHEREAS, the parties desire to amend the Agreement as set forth herein;

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. All terms used in this Amendment and not otherwise defined herein shall have the same meanings ascribed to them in the Agreement.
2. Amendments.
  - (a) Section 3. The Confidential Information of NIAID to be disclosed under the Agreement is hereby amended to include information relating to the human parainfluenza virus (“hPIV”) and related vaccines and assays.
3. All other terms and conditions of the Agreement shall remain unchanged.

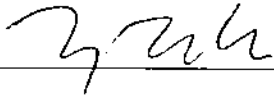
SIGNATURES BEGIN ON NEXT PAGE

IN WITNESS WHEREOF, each party has caused this Amendment No. 1 to Nondisclosure Agreement to be executed by its authorized representative.

Authorized Signatures:

ModernaTX, Inc.

Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health

By: 

By: \_\_\_\_\_

Name: Benjamin Emerson

Name: Carol Salata, Ph.D.

Title: Corporate Counsel

Title: Lead TTPS, TTIPO, NIAID, NIH

Date: 11/16/2016

Date: \_\_\_\_\_



AMENDMENT NO. 3  
TO  
CONFIDENTIAL DISCLOSURE AGREEMENT

This Amendment No. 3 to Nondisclosure Agreement (NIAID Ref. No. 2015-33448) is made as of the 17<sup>th</sup> day of August, 2017 by and between ModernaTX, Inc. (“Moderna”) and the Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health (“NIAID”). Each of Moderna and NIAID may be referred to herein as a “Party” or together as “Parties.”

WHEREAS, Moderna and NIAID entered into a Confidential Disclosure Agreement, dated November 9, 2015 (the “Agreement”) and amended twice effective on October 28, 2016 and November 18, 2016; and

WHEREAS, the Agreement expires on November 9, 2017; and

WHEREAS, the parties desire to amend the Agreement as set forth herein;

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. All terms used in this Amendment and not otherwise defined herein shall have the same meanings ascribed to them in the Agreement.

2. Amendments.

(a) Section 3. The Confidential Information of NIAID to be disclosed under the Agreement is hereby amended to include information relating to the Nipah virus and related vaccines and assays.

(b) Section 10. Section 10 of the Agreement is deleted in its entirety and is replaced with the following:

10. This Agreement will control the disclosure Confidential Information for a disclosure period beginning on the Effective Date and expiring thirty-six (36) months from the Effective Date (i.e. November 9, 2018). Either Party may terminate this Agreement upon thirty (30) days written notice to the other Party, however, each Parties’ obligations of maintaining confidentiality will survive the expiration or earlier termination of this Agreement for a period of five (5) years from the Effective Date.

3. All other terms and conditions of the Agreement shall remain unchanged.

SIGNATURES BEGIN ON NEXT PAGE

IN WITNESS WHEREOF, each party has caused this Amendment No. 3 to Nondisclosure Agreement to be executed by its authorized representative.

Authorized Signatures:

ModernaTX, Inc.

Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health

By: Daphne M. Van de Meerssche

By: CS

Name: Daphne M. Van de Meerssche

Name: Carol Salata, Ph.D.

Title: Counsel, Transactions

Title: Lead TTPS, TTIPO, NIAID, NIH

Date: Aug. 31, 2017

Date: Sept. 1, 2017

**AMENDMENT NO. 4  
TO  
CONFIDENTIAL DISCLOSURE AGREEMENT**

This Amendment No. 4 to Confidential Disclosure Agreement (NIAID Ref. No. 2015-33448) ("Amendment No. 4") is made as of the date of the last authorized signature below ("Amendment No. 4 Effective Date"), by and between ModernaTX, Inc. ("Moderna") and the Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health ("NIAID"). Each of Moderna and NIAID may be referred to herein as a "Party" or together as "Parties."

WHEREAS, Moderna and NIAID entered into a Confidential Disclosure Agreement, dated November 9, 2015 (the "Agreement") and amended thrice effective on October 28, 2016, November 18, 2016, and August 17, 2017; and

WHEREAS, the Agreement expires on November 9, 2018; and

WHEREAS, the parties desire to amend the Agreement as set forth herein,

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. All terms used in this Amendment No. 4 and not otherwise defined herein shall have the same meanings ascribed to them in the Agreement.
2. Amendments:

Section 10. Section 10 of the Agreement is deleted in its entirety and is replaced with the following:

"10. This Agreement will control the disclosure Confidential Information for a disclosure period beginning on the Effective Date and expiring sixty (60) months from the Effective Date (i.e. November 9, 2020). Either Party may terminate this Agreement upon thirty (30) days written notice to the other Party, however, each Parties' obligations of maintaining confidentiality will survive the expiration or earlier termination of this Agreement for a period of Propnetar  
y years from the Effective Date."

3. All other terms and conditions of the Agreement shall remain unchanged.

SIGNATURES BEGIN ON NEXT PAGE

IN WITNESS WHEREOF, each party has caused this Amendment No. 4 to Confidential Disclosure Agreement to be executed by its authorized representative.

**ACCEPTED AND AGREED TO:**

**FOR NIAID:**

Amy F. Petrik -<sup>5</sup>  
Digitally signed by Amy F. Petrik -  
Date: 2018.12.19 15:09:28 -0500

Amy Petrik, Ph.D.  
Senior TTPS, TTIPO, NIAID, NIH

Date

Mailing Address for Notices:  
ATTN: CDA NIAID REF. NO. 2015-33448-4  
TECHNOLOGY TRANSFER AND INTELLECTUAL PROPERTY OFFICE, NIAID  
Suite 6D, MSC 9804, 5601 Fishers Lane  
Rockville, MD 20852  
Tel: 301-496-2644 / Fax: 240-627-3117

**FOR ModernaTX, Inc.**

*Daphne Van de Meerssche*

*Dec 19, 2018*

NAME OF AUTHORIZED SIGNATORY

Date

Mailing Address for Notices:

**Daphne Van de Meerssche  
Counsel, Transactions**

ModernaTX, Inc.  
Attn: General Counsel  
200 Technology Square  
Cambridge, MA 02139

**AMENDMENT NO. 5  
TO  
CONFIDENTIAL DISCLOSURE AGREEMENT**

This Amendment No. 5 to Confidential Disclosure Agreement (NIAID Ref. No. 2015-33448) ("Amendment No. 5") is made as of the date of the last authorized signature below ("Amendment No. 5 Effective Date"), by and between ModernaTX, Inc. ("Moderna") and the Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health ("NIAID"). Each of Moderna and NIAID may be referred to herein as a "Party" or together as "Parties."

WHEREAS, Moderna and NIAID entered into a Confidential Disclosure Agreement, dated November 9, 2015 (the "Agreement") and amended four times, effective on October 28, 2016, November 18, 2016, August 17, 2017, and December 19, 2018; and

WHEREAS, the Agreement expires on November 9, 2020; and

WHEREAS, the parties desire to amend the Agreement as set forth herein.

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. All terms used in this Amendment No. 4 and not otherwise defined herein shall have the same meanings ascribed to them in the Agreement.
2. Amendments:

Section 3. Section 3 of the Agreement is deleted in its entirety and is replaced with the following:

"3. The information disclosed under this Agreement ("Confidential Information") includes any and all technical, business and financial information, including third party information, relating to the Disclosing Party, including but not limited to: (a) nonpublic patent applications; Proprietary Info and (c) other proprietary information, ideas, gene sequences, samples, chemical compounds, biological materials, techniques, works of authorship, non-public inventions, know-how and processes related to the current, future, and proposed products and/or services of the Disclosing Party or its partners, and including without limitation, information concerning research, experimental work, development, design details and specifications, engineering, financial information, procurement requirements, purchasing manufacturing, customer lists, investors, employees, business and contractual relationships, business forecasts, analyst reports, marketing plans and any additional non-public information that the Disclosing Party provides.

The Confidential Information disclosed under this Agreement is described as:

For NIAID: NIAID's proprietary information and data relating to the development of vaccines for HIV, influenza, Ebola, MERS, Nipah, hPIV, hMPV, measles, and mumps and development of broadly neutralizing monoclonal antibodies for prevention and therapeutic use.

For Collaborator: Moderna's proprietary and confidential information related to design and manufacture of a messenger RNA platform and messenger RNA constructs for treatment and prevention of disease.”

3. All other terms and conditions of the Agreement shall remain unchanged.

SIGNATURES BEGIN ON NEXT PAGE

IN WITNESS WHEREOF, each party has caused this Amendment No. 4 to Confidential Disclosure Agreement to be executed by its authorized representative.

**ACCEPTED AND AGREED TO:**

**FOR NIAID:**

\_\_\_\_\_  
Amy Petrik, Ph.D.  
Senior TTPS, TTIPO, NIAID, NIH

\_\_\_\_\_  
Date

Mailing Address for Notices:  
ATTN: CDA NIAID REF. NO. 2015-33448-4  
TECHNOLOGY TRANSFER AND INTELLECTUAL PROPERTY OFFICE, NIAID  
Suite 6D, MSC 9804, 5601 Fishers Lane  
Rockville, MD 20852  
Tel: 301-496-2644 / Fax: 240-627-3117

**FOR ModernaTX, Inc.**

*Daphne M. Van de Meulede*  
\_\_\_\_\_  
NAME OF AUTHORIZED SIGNATORY

*April 26, 2019*  
\_\_\_\_\_  
Date

Mailing Address for Notices:

ModernaTX, Inc.  
Attn: General Counsel  
200 Technology Square  
Cambridge, MA 02139

**AMENDMENT NO. 6  
TO  
CONFIDENTIAL DISCLOSURE AGREEMENT**

This Amendment No. 6 to Confidential Disclosure Agreement (NIAID Ref. No. 2015-33448) ("Amendment No. 6") is made as of the date of the last authorized signature below ("Amendment No. 6 Effective Date"), by and between ModernaTX, Inc. ("Moderna") and the Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health ("NIAID"). Each of Moderna and NIAID may be referred to herein as a "Party" or together as "Parties."

WHEREAS, Moderna and NIAID entered into a Confidential Disclosure Agreement, dated November 9, 2015 (the "Agreement") and amended five times, effective on October 28, 2016, November 18, 2016, August 17, 2017, December 19, 2018 and April 29, 2019; and

WHEREAS, the Agreement expires on November 9, 2020; and

WHEREAS, the parties desire to amend the Agreement as set forth herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. All terms used in this Amendment No. 6 and not otherwise defined herein shall have the same meanings ascribed to them in the Agreement.
2. Amendments:

Section 3. Section 3 of the Agreement is deleted in its entirety and is replaced with the following:

"3. The information disclosed under this Agreement ("Confidential Information") includes any and all technical, business and financial information, including third party information, relating to the Disclosing Party, including but not limited to: (a) nonpublic patent applications; and (b) other proprietary information, ideas, gene sequences, samples, chemical compounds, biological materials, techniques, works of authorship, non-public inventions, know-how and processes related to the current, future, and proposed products and/or services of the Disclosing Party or its partners, and including without limitation, information concerning research, experimental work, development, design details and specifications, engineering, financial information, procurement requirements, purchasing manufacturing, customer lists, investors, employees, business and contractual relationships, business forecasts, analyst reports, marketing plans and any additional non-public information that the Disclosing Party provides.

The Confidential Information disclosed under this Agreement is described as:



For NIAID: NIAID’s proprietary information and data relating to the development of vaccines for HIV, influenza, Ebola, MERS, Nipah, hPIV, hMPV, measles, mumps and picornoviruses and development of broadly neutralizing monoclonal antibodies for prevention and therapeutic use.

For Collaborator: Moderna’s proprietary and confidential information related to design and manufacture of a messenger RNA platform and messenger RNA constructs for treatment and prevention of disease, including without limitation, the design and manufacture of a messenger RNA platform and messenger RNA constructs related to the diseases referenced in this Section.”

3. All other terms and conditions of the Agreement shall remain unchanged.

SIGNATURES BEGIN ON NEXT PAGE

IN WITNESS WHEREOF, each party has caused this Amendment No. 4 to Confidential Disclosure Agreement to be executed by its authorized representative.

**ACCEPTED AND AGREED TO:**

**FOR NIAID:**

**Amy F. Petrik -S**

Digitally signed by Amy F. Petrik  
-S  
Date: 2020.01.22 08:06:55 -05'00'

Amy Petrik, Ph.D.  
Senior TTPS, TTIPO, NIAID, NIH

\_\_\_\_\_  
Date

Mailing Address for Notices:

ATTN: CDA NIAID REF. NO. 2015-33448-4  
TECHNOLOGY TRANSFER AND INTELLECTUAL PROPERTY OFFICE, NIAID  
Suite 6D, MSC 9804, 5601 Fishers Lane  
Rockville, MD 20852  
Tel: 301-496-2644 / Fax: 240-627-3117

**FOR ModernaTX, Inc.**

DocuSigned by:  
*Khalil Mitchell*  
2320B829F722453

Corporate Counsel

2/4/2020

\_\_\_\_\_  
NAME OF AUTHORIZED SIGNATORY

\_\_\_\_\_  
Date

Mailing Address for Notices:

ModernaTX, Inc.  
Attn: General Counsel  
200 Technology Square  
Cambridge, MA 02139

## **PUBLIC HEALTH SERVICE**

### **COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT**

This Agreement is based on the model Cooperative Research and Development Agreement (“CRADA”) 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 CRADA:

The U.S. Department of Health and Human Services, as represented by

**National Institute of Allergy and Infectious Diseases (“NIAID”)**

an Institute or Center (hereinafter referred to as the “IC”) of the

**NIH**

and

Moderna Therapeutics, Inc.

hereinafter referred to as the “**Collaborator**”,  
having offices at 320 Bent Street, Cambridge, MA 02141,  
created and operating under the laws of the State of Delaware.

# COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

## Article 1. Introduction

This CRADA between IC and Collaborator will be effective when signed by the Parties, which are identified on both the Cover Page and the Signature Page. The official contacts for the Parties are identified on the Contacts Information Page. Publicly available information regarding this CRADA appears on the Summary Page. The research and development activities that will be undertaken by IC and Collaborator in the course of this CRADA are detailed in the Research Plan, attached as Appendix A. The staffing, funding, and materials contributions of the Parties are set forth in Appendix B. Any changes to the model CRADA are set forth in Appendix C.

## Article 2. Definitions

The terms listed in this Article will carry the meanings indicated throughout the CRADA. To the extent a definition of a term as provided in this Article is inconsistent with a corresponding definition in the applicable sections of either the United States Code (U.S.C.) or the Code of Federal Regulations (C.F.R.), the definition in the U.S.C. or C.F.R. will control.

- 2.1 “**Affiliate**” means any corporation or other business entity controlled by, controlling, or under common control with Collaborator at any time during the term of the CRADA. For this purpose, “control” means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or at least fifty percent (50%) interest in the income of the corporation or other business entity.
- 2.2 “**Background Invention**” means an Invention conceived and first actually reduced to practice before the Effective Date of Proprietary Info  
Proprietary Info
- 2.3 “**Collaborator Materials**” means all tangible materials not first produced in the performance of the Research Plan that are owned or controlled by Collaborator and used in the performance of the Research Plan.
- 2.4 “**Confidential Information**” means confidential scientific, business, or financial information disclosed or made available by or on behalf of a Party or its Affiliates to the other Party or its Affiliates provided that the information does not include:
- (a) information that is publicly known or that is available from public sources through no fault of the receiving Party;
  - (b) information that has been made publicly available by its owner;
  - (c) information that receiving Party can establish is already known by the receiving Party, or information that is independently created or compiled by the receiving Party without reference to or use of the provided information; or
  - (d) information that relates to potential hazards or cautionary warnings associated with the production, handling, or use of the subject matter of the Research Plan.

- 2.5 “**Cooperative Research and Development Agreement**” or “**CRADA**” means this Agreement, entered into pursuant to the Federal Technology Transfer Act of 1986, as amended (15 U.S.C. §§ 3710a *et seq.*), and Executive Order 12591 of April 10, 1987.
- 2.6 “**CRADA Data**” means all recorded information first produced in the performance of the Research Plan. Proprietary Info  
Proprietary Info
- 2.7 “**CRADA Materials**” means all new tangible materials first produced in the performance of the Research Plan other than CRADA Data.
- 2.8 “**CRADA Subject Invention**” means any Invention of either or both Parties, conceived or first actually reduced to practice in the performance of the Research Plan.
- 2.9 “**Effective Date**” means the date of the last signature of the Parties executing this Agreement.
- 2.10 “**Government**” means the Government of the United States of America.
- 2.11 “**IC Materials**” means all tangible materials not first produced in the performance of this CRADA that are owned or controlled by IC and used in the performance of the Research Plan.
- 2.12 “**Invention**” means any invention or discovery that is or may be patentable or otherwise protected under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act, 7 U.S.C. §§ 2321 *et seq.*
- 2.13 “**Patent Application**” means an application for patent protection for a CRADA Subject Invention with the United States Patent and Trademark Office (“U.S.P.T.O.”) or the corresponding patent-issuing authority of another nation.
- 2.14 “**Patent**” means any issued United States patent, any international counterpart(s), and any corresponding grant(s) by a non-U.S. government in place of a patent.
- 2.15 “**Principal Investigator(s)**” or “**PI(s)**” means the person(s) designated by the Parties who will be responsible for the scientific and technical conduct of the Research Plan.
- 2.16 “**Research Plan**” means the statement in Appendix A of the respective research and development commitments of the Parties.

### **Article 3. Cooperative Research and Development**

- 3.1 **Performance of Research and Development.** The research and development activities to be carried out under this CRADA will be performed solely by IC and Collaborator (including Valera LLC or another Affiliate of the Collaborator) unless specifically stated elsewhere in this Agreement. The PIs will be responsible for the scientific and technical conduct of this project on behalf of their employers. Any Collaborator employees who will work at IC facilities will be required to sign an agreement appropriately modified in view of the terms of this CRADA.
- 3.2 **Research Plan.** The Parties recognize that the Research Plan describes the collaborative research and development activities they will undertake and that interim research goals set forth in the Research Plan are good faith guidelines. Should events occur that require modification of these goals, then by mutual agreement the Parties can modify them through an amendment, according to Paragraph 13.6.
- 3.3 **Use and Disposition of Collaborator Materials and IC Materials.** The Parties agree to use Collaborator Materials and IC Materials only in accordance with the Research Plan, not to transfer these materials to, Proprietary Info third parties except in accordance with the Research Plan or as approved by the owning or providing Party, and, upon expiration or termination of the CRADA, to dispose of these materials as directed by the owning or providing Party.
- 3.4 **Third-Party Rights in Collaborator's CRADA Subject Inventions.** If Collaborator has received (or will receive) support of any kind from a third party in exchange for rights in any of Collaborator's CRADA Subject Inventions, Collaborator agrees to ensure that its obligations to the third party are both consistent with Articles 6 through 8 and subordinate to Article 7 of this CRADA.
- 3.5 **Disclosures to IC.** Prior to execution of this CRADA, Collaborator agrees to disclose to IC all instances in which outstanding royalties are due under a PHS license agreement, and in which Collaborator had a PHS license terminated in accordance with 37 C.F.R. § 404.10. These disclosures will be treated as Confidential Information upon request by Collaborator in accordance with Paragraphs 2.4, 8.3, and 8.4.

#### **Article 4. Reports**

- 4.1 **Interim Research and Development Reports.** The PIs should exchange information regularly, in writing. This exchange may be accomplished through meeting minutes, annual reports, detailed correspondence, and circulation of draft manuscripts.
- 4.2 **Final Research and Development Reports.** The Parties will exchange final reports of their results within four (4) months after the expiration or termination of this CRADA. These reports will set forth the technical progress made; any publications arising from the research; and the existence of invention disclosures of potential CRADA Subject Inventions and/or any corresponding Patent Applications.

- 4.3 **Fiscal Reports.** If Collaborator has agreed to provide funding to IC under this CRADA and upon the request of Collaborator, then concurrent with the exchange of final research and development reports according to Paragraph 4.2, IC will submit to Collaborator a statement of all costs incurred by IC for the CRADA. If the CRADA has been terminated, IC will specify any costs incurred before the date of termination for which IC has not received funds from Collaborator, as well as for all reasonable termination costs including the cost of returning Collaborator property or removal of abandoned Collaborator property, for which Collaborator will be responsible.

## **Article 5. Staffing, Financial, and Materials Obligations**

- 5.1 **IC and Collaborator Contributions.** The contributions of any staff, funds, materials, and equipment by the Parties are set forth in Appendix B. The Federal Technology Transfer Act of 1986, 15 U.S.C. § 3710a(d)(1) prohibits IC from providing funds to Collaborator for any research and development activities under this CRADA.
- 5.2 **IC Staffing.** No IC employees will devote 100% of their effort or time to the research and development activities under this CRADA. IC will not use funds provided by Collaborator under this CRADA for IC personnel to pay the salary of any permanent IC employee. Although personnel hired by IC using CRADA funds will focus principally on CRADA research and development activities, Collaborator acknowledges that these personnel may nonetheless make contributions to other research and development activities, and the activities will be outside the scope of this CRADA.
- 5.3 **Collaborator Funding.** Collaborator acknowledges that Government funds received by Collaborator from an agency of the Department of Health and Human Services may not be used to fund IC under this CRADA. If Collaborator has agreed to provide funds to IC then the payment schedule appears in Appendix B and Collaborator will make payments according to that schedule. If Collaborator fails to make any scheduled payment, IC will not be obligated to perform any of the research and development activities specified herein or to take any other action required by this CRADA until the funds are received. IC will use these funds exclusively for the purposes of this CRADA. Each Party will maintain separate and distinct current accounts, records, and other evidence supporting its financial obligations under this CRADA and, upon written request, will provide the other Party a Fiscal Report according to Paragraph 4.3, which delineates all payments made and all obligated expenses, along with the Final Research Report described in Paragraph 4.2.
- 5.4 **Capital Equipment.** Collaborator's commitment, if any, to provide IC with capital equipment to enable the research and development activities under the Research Plan appears in Appendix B. If Collaborator transfers to IC the capital equipment or provides funds for IC to purchase it, then IC will own the equipment. If Collaborator loans capital equipment to IC for use during the CRADA, Collaborator will be responsible for paying all costs and fees associated with the transport, installation, maintenance, repair, removal, or disposal of the equipment, and IC will not be liable for any damage to the equipment.

## Article 6. Intellectual Property

- 6.1 **Ownership of CRADA Subject Inventions, CRADA Data, and CRADA Materials.** Subject to the Government license described in Paragraph 7.5, the sharing requirements of Paragraph 8.1, and the regulatory filing requirements of Paragraph 8.2, the producing Party will retain sole ownership of and title to all copies of CRADA Data, and all CRADA Materials produced solely by its employee(s). The Parties will own jointly all copies of CRADA Data and all CRADA Materials developed jointly. Ownership of all CRADA Subject Inventions will follow inventorship, which will be determined in accordance with U.S. patent law. CRADA Subject Inventions made solely by IC employee(s) or by employee(s) of Collaborator shall be owned by the Government or Collaborator, respectively. CRADA Subject Inventions made jointly by IC employee(s) and employee(s) of Collaborator shall be jointly-owned by the Government and Collaborator.

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- 6.2 **Reporting.** The Parties will promptly report to each other in writing, generally within 60 days, each CRADA Subject Invention reported by their respective personnel, and any Patent Applications filed thereon, resulting from the performance of the Research Plan. Each Party will report all CRADA Subject Inventions to the other Party in sufficient detail to determine inventorship, which will be determined in accordance with U.S. patent law. These reports will be treated as Confidential Information in accordance with Article 8. Formal reports will be made by and to the Patenting and Licensing Offices identified on the Contacts Information Page herein.
- 6.3 **Filing of Patent Applications.** Each Party will make timely decisions regarding the filing of Patent Applications on the CRADA Subject Inventions made solely by its employee(s), and will notify the other Party in advance of filing. Collaborator will have the first opportunity to file a Patent Application on joint CRADA Subject Inventions and will notify PHS of its decision within sixty (60) days of an Invention being reported or at least thirty (30) days before any patent filing deadline, whichever occurs sooner. If Collaborator fails to notify PHS of its decision within that time period or notifies PHS of its decision not to file a Patent Application, then PHS has the right to file a Patent Application on the joint CRADA Subject Invention. Neither Party will be obligated to file a Patent Application. Collaborator will place the following statement in any Patent Application it files on a CRADA Subject Invention: "This invention was created in the performance of a Cooperative Research and Development Agreement with the National Institutes of Health, an Agency of the Department of Health and Human Services. The Government of the United States has certain rights in this invention." If either Party files a Patent Application on a joint CRADA Subject Invention, then the filing Party will include a statement within the Patent Application that clearly identifies the Parties and states that the joint CRADA Subject Invention was made under this CRADA.
- 6.4 **Patent Expenses.** Unless agreed otherwise, the Party filing a Patent Application will be responsible for all expenses and fees in connection with the preparation, filing,



prosecution, and maintenance of any Patent applications and Patents. If a license to any CRADA Subject Invention is granted to Collaborator, then Collaborator will be responsible for all expenses and fees, past and future, in connection with the preparation, filing, prosecution, and maintenance of any Patent Applications and Patents claiming exclusively-licensed CRADA Subject Inventions and will be responsible for a pro-rated share, divided equally among all licensees, of those expenses and fees for non-exclusively licensed CRADA Subject Inventions. Collaborator may waive its exclusive option rights at any time, and incur no subsequent financial obligation for those Patent Application(s) or Patent(s)

- 6.5 **Prosecution of Patent Applications.** The Party filing a Patent Application will provide the non-filing Party with a copy of any official communication relating to prosecution of the Patent Application within thirty (30) days of transmission of the communication. Each Party will also provide the other Party with the power to inspect and make copies of all documents retained in the applicable Patent Application or Patent file. The Parties agree to consult with each other regarding the prosecution of Patent Applications directed to joint CRADA Subject Inventions. Proprietary Info

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If Collaborator elects to file and prosecute Patent Applications on joint CRADA Subject Inventions, then Collaborator agrees to use the U.S.P.T.O. Customer Number Practice and/or grant PHS a power(s) of attorney (or equivalent) necessary to assure PHS access to its intellectual property rights in these Patent Applications. PHS and Collaborator will cooperate with each other to obtain necessary signatures on Patent Applications, assignments, or other documents. Proprietary Info

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## Article 7. Licensing

- 7.1 **Background Inventions.** Other than as specifically stated in this Article 7, nothing in this CRADA will be construed to grant any rights in one Party's Background Invention(s) to the other Party, except to the extent necessary for the Parties to conduct the research and development activities described in the Research Plan.
- 7.2 **Collaborator's License Option to CRADA Subject Inventions.** With respect to Government rights to any CRADA Subject Invention made (i) solely by an IC employee(s) for which a Patent Application was filed, PHS hereby grants to Collaborator an exclusive option to elect an exclusive or nonexclusive development and commercialization license and (ii) jointly by an IC employee(s) and an employee(s) of Collaborator for which a Patent Application was filed, PHS hereby grants to Collaborator an exclusive option to elect an exclusive development and commercialization license under the Government's rights to such jointly made Invention. The license will be substantially in the form of the appropriate model PHS license agreement and will fairly reflect the nature of the CRADA Subject Invention, the relative contributions of the

Parties to the CRADA Subject Invention and the CRADA, a plan for the development and marketing of the CRADA Subject Invention, the risks incurred by Collaborator, and the costs of subsequent research and development needed to bring the CRADA Subject Invention to the marketplace. The field of use of the license will not exceed the scope of the Research Plan.

- 7.3 **Exercise of Collaborator's License Option.** To exercise the option of Paragraph 7.2 Collaborator must submit a written notice to the PHS Patenting and Licensing Contact identified on the Contacts Information Page (and provide a copy to the IC Contact for CRADA Notices) within three (3) months after either (i) Collaborator receives written notice from PHS that the Patent Application has been filed or (ii) the date on which Collaborator files the Patent Application. The written notice exercising this option will include a completed "Application for License to Public Health Service Inventions" and will initiate a negotiation period that expires **Proprietary Info** after the exercise of the option. If PHS has not responded in writing to the last proposal by Collaborator within this **Proprietary Info** period, the negotiation period will be extended to expire two (2) months after PHS so responds, during which period the Parties will work diligently and in good faith to finalize the agreement. In the absence of Collaborator's exercise of the option, or upon election of a nonexclusive license, PHS will be free to license the CRADA Subject Invention to others. These time periods may be extended at the sole discretion of PHS upon good cause shown in writing by Collaborator.
- 7.4 **Government License in IC Sole CRADA Subject Inventions and Joint CRADA Subject Inventions.** Pursuant to 15 U.S.C. § 3710a(b)(1)(A), for CRADA Subject Inventions owned solely by IC or jointly by IC and Collaborator, and licensed pursuant to the option of Paragraph 7.2, Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the CRADA Subject Invention or have the CRADA Subject Invention practiced throughout the world by or on behalf of the Government. In the exercise of this license, the Government will not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. § 552(b)(4) or which would be considered privileged or confidential if it had been obtained from a non-federal party.
- 7.5 **Government License in Collaborator Sole CRADA Subject Inventions.** Pursuant to 15 U.S.C. § 3710a(b)(2), for CRADA Subject Inventions made solely by an employee of Collaborator, Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the CRADA Subject Invention or **Proprietary Info** **Proprietary Info** have the CRADA Subject Invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.
- 7.6 **Third Party License.** Pursuant to 15 U.S.C. § 3710a(b)(1)(B), if PHS grants to Collaborator and its Affiliates an exclusive license to a CRADA Subject Invention made solely by an IC employee or jointly with a Collaborator employee, the Government will retain the right to require Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the CRADA Subject Invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances;

or, if Collaborator fails to grant a license, to grant the license itself. The exercise of these rights by the Government will only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator, (ii) the action is necessary to meet requirements for public use specified by federal regulations, and such requirements are not reasonably satisfied by Collaborator; or (iii) Collaborator has failed to comply with an agreement containing provisions described in 15 U.S.C. § 3710a(c)(4)(B). The determination made by the Government under this Paragraph is subject to administrative appeal and judicial review under 35 U.S.C. § 203(b).

- 7.7 **Third-Party Rights in IC Sole CRADA Subject Inventions.** For a CRADA Subject Invention conceived prior to the Effective Date solely by an IC employee that is first actually reduced to practice after the Effective Date in the performance of the Research Plan, the option offered to Collaborator in Paragraph 7.2 may be restricted if, before the Effective Date, PHS had filed a Patent Application and has either offered or granted a license or has executed a license in the CRADA Subject Invention to a third party. Collaborator nonetheless retains the right to apply for a license to any such CRADA Subject Invention in accordance with the terms and procedures of 35 U.S.C. § 209 and 37 C.F.R. Part 404.

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Proprietary Info

7.9

## Article 8. Rights of Access and Publication

- 8.1 **Right of Access to CRADA Data and CRADA Materials.** IC and Collaborator agree to promptly exchange all CRADA Data and to share all CRADA Materials.
- 8.2 **Use of CRADA Data and CRADA Materials.** The Parties will be free to utilize CRADA Data and CRADA Materials internally for their own purposes, consistent with their obligations under this CRADA. The Parties may share CRADA Data or CRADA Materials with their Affiliates, agents, contractors, provided the obligations of this Article 8.2 are simultaneously conveyed. For clarity, no rights under any Patents are granted by one Party to the other Party by operation of this Section 8.2.

### (a) CRADA Data.

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the extent permitted by law, each Party will have the right to use any and all CRADA Data in and for any regulatory filing by or on behalf of the Party. Proprietary Info

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(b) **CRADA Materials.**

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Without limiting the foregoing, Collaborator acknowledges that the basic research mission of PHS includes sharing with third parties for further research those research resources made in whole or in part with NIH funding. Consistent with this mission and the tenets articulated in “Sharing of Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts”, December 1999, available at [http://www.ott.nih.gov/policy/research\\_tool.aspx](http://www.ott.nih.gov/policy/research_tool.aspx), following publication either Party may make available to third parties for further research those CRADA Materials made jointly by both PHS and Collaborator. Notwithstanding the above, if those joint CRADA Materials are the subject of a pending Patent Application or a Patent, the Parties may agree to restrict distribution or freely distribute them. Either Party may distribute those CRADA Materials made solely by the other Party only upon written consent from that other Party or that other Party’s designee. Proprietary Info

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8.3 **Confidential Information.** Each Party agrees to limit its disclosure of Confidential Information to the amount necessary to carry out the Research Plan, and will place a confidentiality notice on all such information. A Party orally disclosing Confidential Information to the other Party will summarize the disclosure in writing and provide it to the other Party within fifteen (15) days of the disclosure. Notwithstanding the above, failure to mark information as “confidential” will not disqualify that information from constituting “Confidential Information” under this Agreement if a reasonable person would consider such information to be confidential based on the nature of such information and the circumstances of disclosure. Each Party receiving Confidential Information agrees to use it only for the purposes described in the Research Plan. Either

Party may object to the designation of information as Confidential Information by the other Party.

8.4 **Protection of Confidential Information.** Confidential Information will not be disclosed, copied, reproduced or otherwise made available to any other person or entity without the consent of the owning or providing Party except as required by a court or administrative body of competent jurisdiction, or federal law or regulation; provided, however, that Collaborator may disclose Confidential Information to its Affiliates, employees, agents, who have signed confidentiality agreements or are otherwise bound by confidentiality obligations at least as restrictive as those contained herein. Each Party agrees to use reasonable efforts to maintain the confidentiality of Confidential Information, which will in no instance be less effort than the Party uses to protect its own Confidential Information. Each Party agrees that a Party receiving Confidential Information will not be liable for the disclosure of that portion of the Confidential Information which, after notice to and consultation with the disclosing Party, the receiving Party determines may not be lawfully withheld, provided the disclosing Party has been given a reasonable opportunity to seek a court order to enjoin disclosure.

8.5 **Protection of Human Subjects' Information.** The research and development activities to be conducted under this CRADA are not intended to involve human subjects or human tissues within the meaning of 45 C.F.R. Part 46 and 21 C.F.R. Part 50. Should it become necessary to utilize human subjects or human tissues, or to provide a Party with access to information about identifiable human subjects, the Parties agree to amend this CRADA in accordance with Paragraph 13.6 to ensure that the research and development activities conducted hereunder will conform to the appropriate federal laws and regulations, including but not limited to all applicable FDA regulations and HHS regulations relating to the protection of human subjects.

8.6 **Duration of Confidentiality Obligation.** The obligation to maintain the confidentiality of Confidential Information will expire at the earlier of the date when the information is no longer Confidential Information as defined in Paragraph 2.4 or three (3) years after the expiration or termination date of this CRADA. Collaborator may request an extension to this term when necessary to protect Confidential Information relating to products not yet commercialized.

8.7 **Publication.** Proprietary Info the Parties are encouraged to make publicly available the results of their research and development activities hereunder. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about a CRADA Subject Invention, CRADA Data or CRADA Materials, the other Party will have thirty (30) days to review the proposed publication or disclosure to assure that Confidential Information is protected. Proprietary Info

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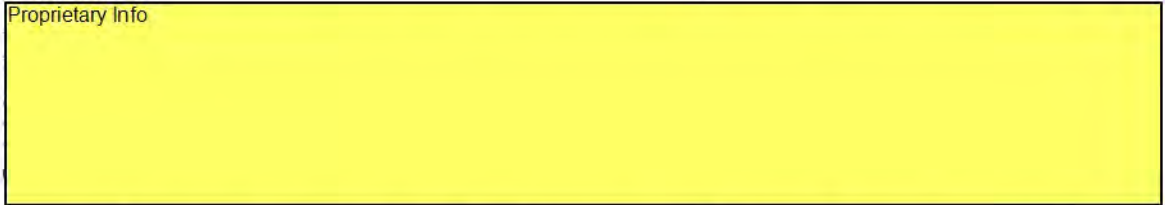
request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to file a Patent Application.

## **Article 9. Representations and Warranties**

9.1 **Representations of IC.** IC hereby represents to Collaborator that:

- (a) IC has the requisite power and authority to enter into this CRADA and to perform according to its terms, and that IC's official signing this CRADA has authority to do so.
- (b) To the best of its knowledge and belief, neither IC nor any of its personnel involved in this CRADA is presently subject to debarment or suspension by any agency of the Government which would directly affect its performance of the CRADA. Should IC or any of its personnel involved in this CRADA be debarred or suspended during the term of this CRADA, IC will notify Collaborator within thirty (30) days of receipt of final notice.

(c) Proprietary Info



9.2 **Representations and Warranties of Collaborator.** Collaborator hereby represents and warrants to IC that:

- (a) Collaborator has the requisite power and authority to enter into this CRADA and to perform according to its terms, and that Collaborator's official signing this CRADA has authority to do so.
- (b) Neither Collaborator nor any of its personnel involved in this CRADA, including Affiliates, agents, and contractors are presently subject to debarment or suspension by any agency of the Government. Should Collaborator or any of its personnel involved in this CRADA be debarred or suspended during the term of this CRADA, Collaborator will notify IC within thirty (30) days of receipt of final notice.
- (c) Subject to Paragraph 12.3, and if and to the extent Collaborator has agreed to provide funding under Appendix B, Collaborator is financially able to satisfy these obligations in a timely manner.

## **Article 10. Expiration and Termination**

10.1 **Expiration.** This CRADA will expire on the last date of the term set forth on the Summary Page. In no case will the term of this CRADA extend beyond the term indicated on the Summary Page unless it is extended in writing in accordance with Paragraph 13.6.

- 10.2 **Termination by Mutual Consent.** IC and Collaborator may terminate this CRADA at any time by mutual written consent.
- 10.3 **Unilateral Termination.** Either IC or Collaborator may unilaterally terminate this CRADA at any time by providing written notice at least sixty (60) days before the desired termination date. IC may, at its option, retain funds transferred to IC before unilateral termination by Collaborator.
- 10.4 **Funding for IC Personnel.** If Collaborator has agreed to provide funding for IC personnel and this CRADA is mutually or unilaterally terminated by Collaborator before its expiration, then Collaborator agrees that funds for that purpose will be available to IC for a period of six (6) months after the termination date or until the expiration date of the CRADA, whichever occurs sooner. If there are insufficient funds to cover this expense, Collaborator agrees to pay the difference.
- 10.5 **New Commitments.** Neither Party will incur new expenses related to this CRADA after expiration, mutual termination, or a notice of a unilateral termination and will, to the extent feasible, cancel all outstanding commitments and contracts by the termination date. Collaborator acknowledges that IC will have the authority to retain and expend any funds for up to one (1) year subsequent to the expiration or termination date to cover any unpaid costs obligated during the term of the CRADA in undertaking the research and development activities set forth in the Research Plan.

## Article 11. Disputes

- 11.1 **Settlement.** Any dispute arising under this CRADA which is not disposed of by agreement of the Principal Investigators will be submitted jointly to the signatories of this CRADA. If the signatories, or their designees, are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the Assistant Secretary for Health (or his/her designee or successor) will propose a resolution. Nothing in this Paragraph will prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.
- 11.2 **Continuation of Work.** Pending the resolution of any dispute or claim pursuant to this Article 11, the Parties agree that performance of all obligations will be pursued diligently.

## Article 12. Liability

- 12.1 **NO WARRANTIES.** EXCEPT AS SPECIFICALLY STATED IN ARTICLE 9, THE PARTIES MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO ANY MATTER WHATSOEVER, INCLUDING THE CONDITIONS OF THE RESEARCH OR ANY INVENTION OR MATERIAL, WHETHER TANGIBLE OR INTANGIBLE, MADE OR DEVELOPED UNDER OR OUTSIDE THE SCOPE OF THIS CRADA, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY INVENTION OR MATERIAL, OR THAT

A TECHNOLOGY UTILIZED BY A PARTY IN THE PERFORMANCE OF THE RESEARCH PLAN DOES NOT INFRINGE ANY THIRD-PARTY PATENT RIGHTS.

- 12.2 **Indemnification and Liability.** Collaborator agrees to hold the Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of the use by Collaborator for any purpose of the CRADA Data, CRADA Materials or CRADA Subject Inventions produced in whole or part by IC employees under this CRADA, unless due to the negligence or willful misconduct of IC, its employees, or agents. The Government has no statutory authority to indemnify Collaborator. Each Party otherwise will be liable for any claims or damages it incurs in connection with this CRADA, except that IC, as an agency of the Government, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. Chapter 171.
- 12.3 **Force Majeure.** Neither Party will be liable for any unforeseeable event beyond its reasonable control and not caused by its own fault or negligence, which causes the Party to be unable to perform its obligations under this CRADA, and which it has been unable to overcome by the exercise of due diligence. If a *force majeure* event occurs, the Party unable to perform will promptly notify the other Party. It will use its best efforts to resume performance as quickly as possible and will suspend performance only for such period of time as is necessary as a result of the *force majeure* event.

### Article 13. Miscellaneous

- 13.1 **Governing Law.** The construction, validity, performance and effect of this CRADA will be governed by U.S. federal law, as applied by the federal courts in the District of Columbia. If any provision in this CRADA conflicts with or is inconsistent with any U.S. federal law or regulation, then the U.S. federal law or regulation will preempt that provision.
- 13.2 **Compliance with Law.** IC and Collaborator agree that they will comply with, and advise their contractors and agents to comply with, all applicable statutes, Executive Orders, HHS regulations, and all FDA, CDC, and NIH policies relating to research on human subjects (45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56) and relating to the appropriate care and use of laboratory animals (7 U.S.C. §§ 2131 *et seq.*; 9 C.F.R. Part 1, Subchapter A). Additional information on these subjects is available from the HHS Office for Human Research Protections or from the NIH Office of Laboratory Animal Welfare. Collaborator agrees to ensure that employees, contractors, and agents of Collaborator who might have access to a “select agent or toxin” (as that term is defined in 42 C.F.R. §§ 73.4-73.5) transferred from IC is properly licensed to receive the “select agent or toxin”.
- 13.3 **Waivers.** None of the provisions of this CRADA will be considered waived by any Party unless a waiver is given in writing to the other Party. The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to



exercise any rights provided herein or by law, will not be deemed a waiver of any rights of any Party.

- 13.4 **Headings.** Titles and headings of the articles and paragraphs of this CRADA are for convenient reference only, do not form a part of this CRADA, and will in no way affect its interpretation.
- 13.5 **Severability.** The illegality or invalidity of any provisions of this CRADA will not impair, affect, or invalidate the other provisions of this CRADA.
- 13.6 **Amendments.** Minor modifications to the Research Plan may be made by the mutual written consent of the Principal Investigators. Substantial changes to the CRADA, extensions of the term, or any changes to Appendix C will become effective only upon a written amendment signed by the signatories to this CRADA or by their representatives duly authorized to execute an amendment. A change will be considered substantial if it directly expands the range of the potential CRADA Subject Inventions, alters the scope or field of any license option governed by Article 7, or requires a significant increase in the contribution of resources by either Party.
- 13.7 **Assignment.** Neither this CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party Proprietary Info  
Proprietary Info  
Parties agree that the identity of the Collaborator is material to the performance of this CRADA and that the duties under this CRADA are nondelegable, except as otherwise provided in Article 3.1.
- 13.8 **Notices.** All notices pertaining to or required by this CRADA will be in writing, signed by an authorized representative of the notifying Party, and delivered by first class, registered, or certified mail, or by an express/overnight commercial delivery service, prepaid and properly addressed to the other Party at the address designated on the Contacts Information Page, or to any other address designated in writing by the other Party. Notices will be considered timely if 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. Notices regarding the exercise of license options will be made pursuant to Paragraph 7.3. Either Party may change its address by notice given to the other Party in the manner set forth above.
- 13.9 **Independent Contractors.** The relationship of the Parties to this CRADA is that of independent contractors and not agents of each other or joint venturers or partners. Each Party will maintain sole and exclusive control over its personnel and operations.
- 13.10 **Use of Name; Press Releases.** By entering into this CRADA, the Government does not directly or indirectly endorse any product or service that is or will be provided, whether

directly or indirectly related to either this CRADA or to any patent or other intellectual-property license or agreement that implements this CRADA by Collaborator, its successors, assignees, or licensees. Collaborator will not in any way state or imply that the Government or any of its organizational units or employees endorses any product or service. Each Party agrees to provide proposed press releases that reference or rely upon the work under this CRADA to the other Party for review and comment at least seven (7) days prior to publication. Either Party may disclose the Summary Page to the public without the approval of the other Party.

- 13.11 **Reasonable Consent.** Whenever a Party's consent or permission is required under this CRADA, its consent or permission will not be unreasonably withheld.
- 13.12 **Export Controls.** Collaborator agrees to comply with U.S. export law and regulations. If Collaborator has a need to transfer any CRADA Materials made in whole or in part by IC, or IC Materials, or IC's Confidential Information, to a person located in a country other than the United States, to an Affiliate organized under the laws of a country other than the United States, or to an employee of Collaborator in the United States who is not a citizen or permanent resident of the United States, Collaborator will acquire any and all necessary export licenses and other appropriate authorizations.
- 13.13 **Entire Agreement.** This CRADA constitutes the entire agreement between the Parties concerning the subject matter of this CRADA and supersedes any prior understanding or written or oral agreement. Specifically, the Confidential Disclosure Agreement (CDA), executed between the Parties on 9 November 2015 (NIAID Ref. No. 2015-33448) is hereby superseded and succeeded by the terms of this CRADA. The confidential information exchanged between the Parties under the CDA shall be governed by the terms of the CRADA as it relates to confidentiality effective as of the date of execution of the CDA.
- 13.14 **Survivability.** The provisions of Paragraphs 3.3, 3.4, 4.2, 4.3, 5.3, 5.4, 6.1-9.2, 10.3-10.5, 11.1, 12.1-12.3, 13.1-13.3, 13.10 and 13.14 will survive the expiration or early termination of this CRADA.

SIGNATURES BEGIN ON THE NEXT PAGE

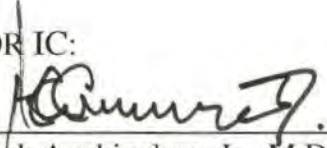
**PUBLIC HEALTH SERVICE  
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT**

**SIGNATURE PAGE**

**ACCEPTED AND AGREED**


BY EXECUTING THIS AGREEMENT, EACH PARTY REPRESENTS THAT ALL STATEMENTS MADE HEREIN ARE TRUE, COMPLETE, AND ACCURATE TO THE BEST OF ITS KNOWLEDGE. COLLABORATOR ACKNOWLEDGES THAT IT MAY BE SUBJECT TO CRIMINAL, CIVIL, OR ADMINISTRATIVE PENALTIES FOR KNOWINGLY MAKING A FALSE, FICTITIOUS, OR FRAUDULENT STATEMENT OR CLAIM.

FOR IC:

  
\_\_\_\_\_  
Hugh Auchincloss, Jr., M.D.  
Principal Deputy Director  
National Institute of Allergy and Infectious Diseases

  
8/15/16  
Date

FOR COLLABORATOR:

  
\_\_\_\_\_  
Stephen Hoge, M.D.  
President, Moderna Therapeutics, Inc.

8/22/2016  
Date

**PUBLIC HEALTH SERVICE  
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT**

**CONTACTS INFORMATION PAGE**

CRADA Notices

For IC:

Michael R. Mowatt, Ph.D.  
Director, Technology Transfer and  
Intellectual Property Office  
National Institute of Allergy and  
Infectious Diseases  
Suite 6D, MSC 9804  
5601 Fishers Lane  
Rockville, MD 20852  
Tel: 301-496-2644  
Fax: 240-627-3117

For Collaborator:

ATTN: Moderna Legal Department  
Moderna Therapeutics, Inc.  
320 Bent Street  
Cambridge, MA 02141

With a copy to:  
Giuseppe (Pino) Ciaramella  
Chief Scientific Officer, Valera LLC  
500 Technology Square, 7<sup>th</sup> Floor  
Cambridge, MA 02139

Patenting and Licensing

For IC:

Division Director, Division of Technology  
Development and Transfer  
NIH Office of Technology Transfer  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804  
Tel: 301-496-7057  
Fax: 301-402-0220

For Collaborator (if separate from above):

Same as above

Delivery of Materials Identified in Appendix B (if any)

For IC:

Barney Graham, MD, PhD  
Building 40 Room 2502  
40 Convent Drive  
Bethesda, MD 20814

Tel: 301-594-8486

For Collaborator:

Giuseppe (Pino) Ciaramella, Ph.D.  
Chief Scientific Officer, Valera LLC  
500 Technology Square, 7<sup>th</sup> Floor  
Cambridge, MA 02139

Tel: (617) 209-5818

**PUBLIC HEALTH SERVICE  
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT**

**SUMMARY PAGE**

EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION,  
RELEASE THIS SUMMARY PAGE TO THE PUBLIC.

**TITLE OF CRADA: The use of Moderna Therapeutic, Inc.'s Proprietary messenger RNA  
technology for the development of HIV-1 vaccine candidates**

PHS IC Component: NIAID  
IC Principal Investigator: Barney Graham, MD, PhD; John Mascola, MD; Richard  
Koup, MD; Peter D. Kwong, PhD

Collaborator: Moderna Therapeutics, Inc.  
Collaborator Principal Investigator: Giuseppe Ciaramella, PhD

TERM OF CRADA: Three (3) years from the Effective Date.

**ABSTRACT OF THE RESEARCH PLAN:**

Under a Cooperative Research and Development Agreement, Moderna Therapeutics, Inc. and the National Institute of Allergy and Infectious Diseases will collaborate to develop vaccine candidates for Human Immunodeficiency Virus type 1 (HIV-1) based on antigens developed by the National Institute of Allergy and Infectious Diseases and using Moderna Therapeutics, Inc.'s propriety mRNA vaccine technology.

## APPENDIX A

### RESEARCH PLAN

#### Title of the CRADA

**The use of Moderna Therapeutics, Inc.'s Proprietary messenger RNA for the development of HIV-1 vaccine candidates**

#### NIAID, NIH Principal Investigator

Barney S. Graham, MD, PhD  
Richard Koup, MD  
Peter D. Kwong, PhD  
John R. Mascola, MD  
Vaccine Research Center, NIAID

#### Collaborator Principal Investigator

Giuseppe Ciaramella, PhD  
Moderna Therapeutics, Inc.

#### Term of CRADA

3 years from the Effective Date

#### GOAL OF THIS CRADA

The principal goal of this CRADA is to identify and optimize the next generation of HIV-1 Proprietary Info vaccine antigens by enabling the accelerated expression and characterization of lead molecules through Moderna's mRNA technology. The gene constructs will be based on the ongoing research on Proprietary antigens by the VRC, described in several publications. The scope of this CRADA, including any *in vitro* and *in vivo* testing conducted by Drs. John Mascola, Rick Koup, Peter Kwong and Barney Graham, members of their laboratories, and other VRC, NIAID investigators is strictly limited to the development and testing of HIV-1 antigen sequences, provided by NIAID, that utilize Moderna's proprietary mRNA constructs.

#### INTRODUCTION

Vaccine development to induce broadly neutralizing antibodies (bNAbs) against HIV-1 is a global health priority. Although potent bNAbs against the Proprietary Info

Proprietary Info have been isolated from HIV-infected individuals, vaccination strategies developed to date have failed to generate similar bNAbs.

Several major factors contribute to the poor antigenicity of Env immunogens, including conformational evasion, immunodominance of non-neutralizing surfaces, glycan shielding of key neutralizing epitopes, and high genetic variation. Generating stabilized, pre-fusion trimer proteins may allow a solution for conformational evasion and immunodominance, and rapid evaluation of iterative designs using mRNA technology may allow the glycosylation and genetic

variation issues to be addressed to achieve the goal of inducing bNAbs.

The aim of this collaboration is to discover antigens that can induce broadly neutralizing antibodies, or stimulate bNAb lineages that can be detected by sequencing of B cell transcripts, following vaccination with Moderna's mRNA technology. Moderna's mRNA technology will be used to accelerate the design-to-test cycle for the discovery of these novel HIV Proprietary antigens, as well as to test the preclinical efficacy of an mRNA vaccine encoding for these proteins.

## **EXPERTISE OF THE PARTIES**

VRC investigators have extensive experience in leading research efforts related to the structural basis of antibody-based virus neutralization and to vaccine development more broadly. Additionally, they have been involved in the design, planning, and execution of numerous clinical trials in virology and immunology, and have been involved with the clinical evaluation of candidate HIV vaccines for over 25 years. NIAID has identified several approaches to stabilizing the trimeric HIV envelope in conformations known to expose neutralization-sensitive epitopes.

Moderna Therapeutics, Inc. ("Moderna"), along with its affiliate focused on infectious disease, Valera LLC ("Valera"), has assembled a highly experienced team of senior level executives and scientists who have extensive experience and a proven track record in the development of vaccines. Moderna's functional expertise includes areas of pre-clinical and clinical research and development, regulatory, manufacturing, and product quality control and assurance. Scientifically, Moderna's team, led by Dr. Giuseppe Ciaramella as Chief Scientific Officer of Valera, has been involved with the development of vaccines across several global leaders in the field, including Pfizer, Merck, Boehringer Ingelheim, Novartis, and AstraZeneca. In addition, the Moderna team has specific experience in selecting, formulating, and validating antigens for encoding in mRNA vaccines. Moderna's vaccine development efforts have spanned various infectious diseases, and include world-class expertise in mRNA construct production optimization, up to and including cGMP drug product manufacturing in order to bring clinical candidates forward through regulatory processes in the US and EU. Moderna's expertise in mRNA vaccines will facilitate and accelerate the development of NIAID's vaccines against HIV-1.

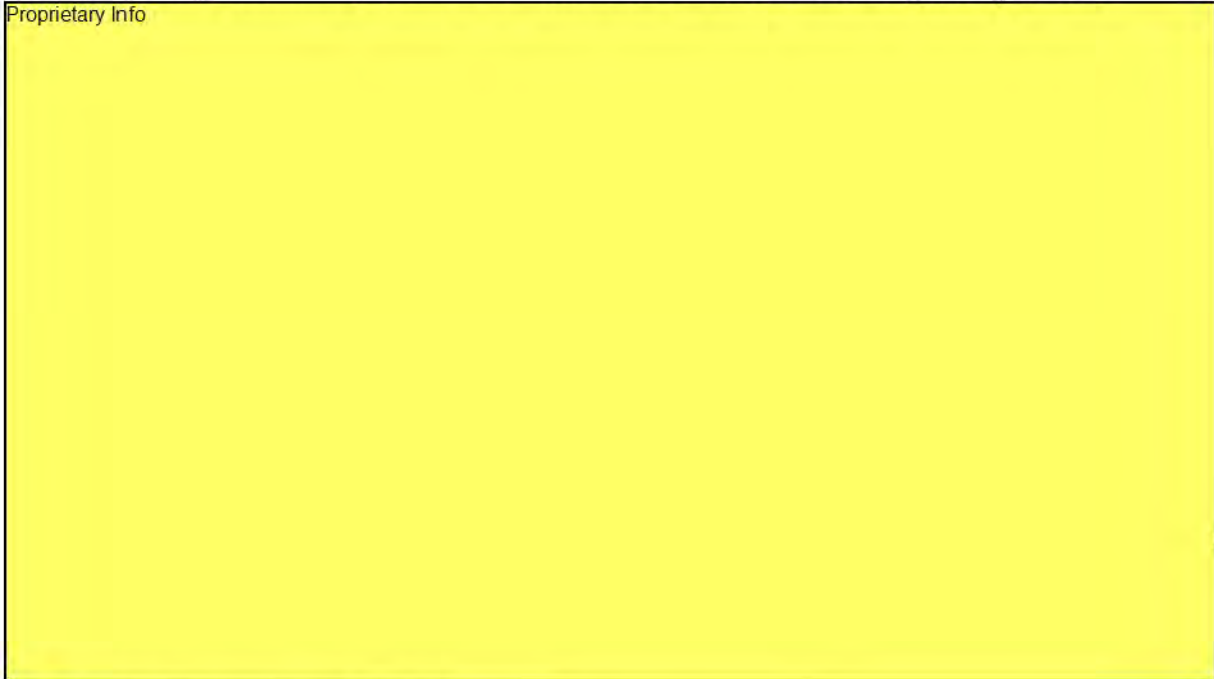
## **EXPERIMENTAL PLAN**

The experimental details that follow are approximate and may be changed upon mutual agreement of NIAID and Moderna. Any substantive change to the Research Plan will be by mutual agreement and written Amendment to this CRADA.

Several steps, listed below, are planned for the identification, production, and functional characterization of antigens that can induce broadly neutralizing antibodies against HIV-1. Broadly, the work is broken out into two phases, with Phase 1 acting as a gating mechanism before initiating Phase 2.

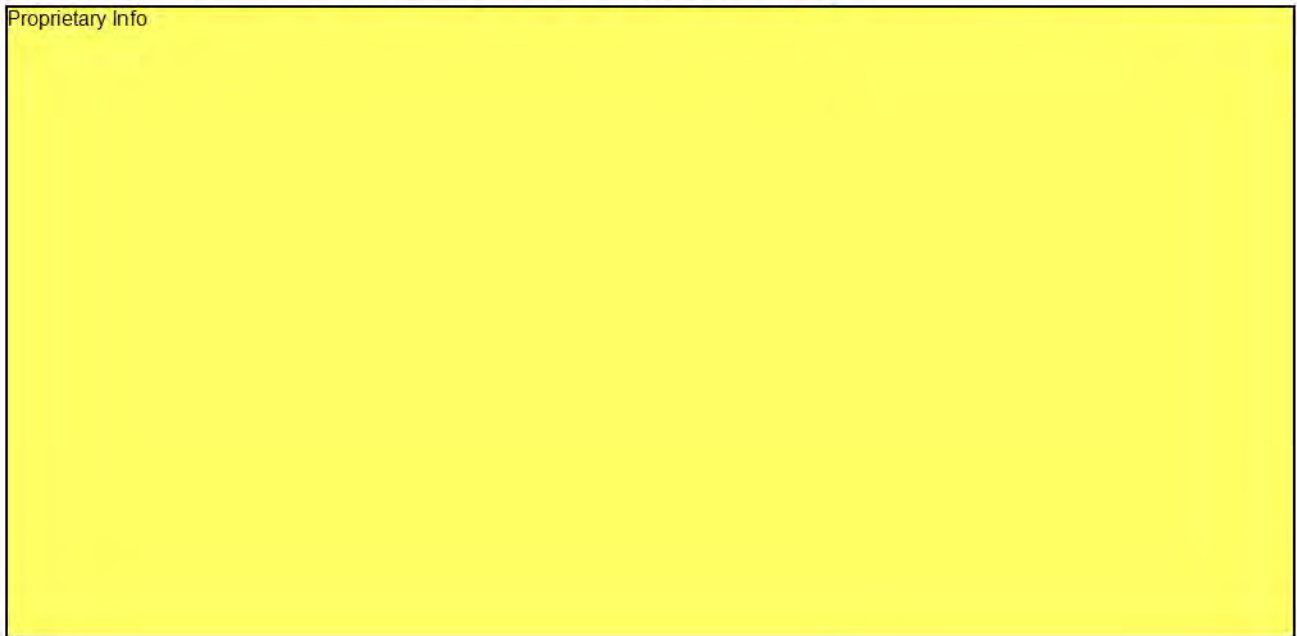
### Phase I: Proof of Concept

The goal of this phase of research is to test the underlying premises of this collaboration, namely: (i) ability of NIAID to design genetic constructs that recapitulate the immunogenicity of soluble trimers, (ii) ability of Moderna to produce vaccine product based on NIAID antigen polypeptide sequences; and (iii) preliminary readout of mRNA HIV vaccine immunogenicity *in vivo*.



Phase 2: Project Expansion – Lead Discovery

Execution of Phase 2 is dependent upon mutual agreement that Phase 1 proof-of-concept was successfully met. The goal of Phase 2 is the iterative production and *in vivo* testing of NIAID antigens, utilizing vaccine-formulated Moderna mRNA constructs.





## DESCRIPTION OF THE CONTRIBUTION AND RESPONSIBILITIES OF THE PARTIES

### Vaccine Research Center, NIAID

- Polypeptide sequences for antigens
- Animal models for in vivo inoculation
- Immune response characterization
- **Proprietary** protein structural and antigenic analysis
- Protein immunogens for **Proprietary Info** regimen studies

### Moderna Therapeutics, Inc.

- mRNA optimization and production
- mRNA vaccine formulation for in vitro transfection and injection into animals

### Vaccine Research Center, NIAID AND Moderna Therapeutics, Inc.

- Evaluate the results from Phase 1 in order to determine which antigen constructs, if any, will proceed to Phase 2

## RELATED NIAID AND COLLABORATOR AGREEMENTS

The Confidential Disclosure Agreement (CDA), executed by the Parties on 9 November 2015 (NIAID Ref. No. 2015-33448) is hereby superseded and succeeded by the terms of this CRADA. The confidential information exchanged between the Parties under the CDA shall be governed by the terms of the CRADA as it relates to confidentiality effective as of the date of execution of the CDA.

## RELATED INTELLECTUAL PROPERTY OF THE PARTIES

### Collaborator Patents and Patent Applications:

The technology Collaborator intends to contribute for the work under the CRADA arises out of a combination of numerous patents and patent families, and not just one (or a few) patents.

### NIAID Patent Applications

PCT/US2015/048729 – filed 4 September 2015, titled, “Recombinant HIV-1 Envelope Proteins and their Use”

## APPENDIX B

### STAFFING, FUNDING, AND MATERIALS/EQUIPMENT CONTRIBUTIONS OF THE PARTIES

#### *Staffing Contributions:*

IC will provide scientific staff and other support necessary to conduct the research and other activities described in the Research Plan. IC's scientific staff will include IC's Principal Investigator and technical staff.

IC estimates that Proprietary Info person-years of effort per year will be required to complete the CRADA research.

Collaborator will provide scientific staff and other support necessary to conduct the research and other activities described in the Research Plan. Collaborator's scientific staff will include Collaborator's Principal Investigator and technical staff.

Collaborator estimates that Proprietary Info person-years of effort per year will be required to complete the CRADA research.

#### *Funding Contributions:*

Collaborator agrees to provide funds in the amount of Proprietary per year of the CRADA for IC to use to acquire technical, statistical, and administrative support for the research activities, as well as to pay for supplies and travel expenses. Collaborator will provide funds in equal annual installments. The first installment will be due within thirty (30) days of the Effective Date. Each subsequent installment will be due within thirty (30) days of each anniversary of the Effective Date. Collaborator agrees that IC can allocate the funding between the various categories in support of the CRADA research as IC sees fit.

#### CRADA PAYMENTS:

Collaborator will make checks payable to the NIAID, will reference the CRADA number and title on each check, and will send them via trackable mail or courier to:

NIAID CRADA Coordinator, TTIPO, NIAID  
5601 Fishers Lane, Suite 6D  
Rockville, MD 20852-9804

#### CRADA Travel Payments:

Travel arrangements for all Government staff will be made in accordance with the Federal Travel Rules and Regulations, whether arranged by IC and funded using either appropriated funds or CRADA funds, or arranged and funded directly by Collaborator.

#### *Materials/Equipment Contributions:*

IC will provide to Collaborator the following IC Materials for use under this CRADA:

Polypeptide sequences for HIV-1 **Proprietary** antigens  
Protein HIV-1 **Proprietary** immunogens, as needed for prime-boost regimens

Collaborator will provide to IC the following Collaborator Materials and/or capital equipment for use under this CRADA:

Collaborator Materials:

mRNA, including mRNA encoding for HIV-1 **Proprietary** antigens  
mRNA vaccine formulation for in vitro transfection studies and in vivo animal studies

Capital Equipment:

None.

If either Party decides to provide additional Materials for use under this CRADA, those Materials will be transferred under a cover letter that identifies them and states that they are being provided under the terms of the CRADA.

## PUBLIC HEALTH SERVICE

## MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement ("MTA") has been adopted for use by the National Institutes of Health, the Food and Drug Administration and the Centers for Disease Control and Prevention, collectively referred to herein as the Public Health Service ("PHS") in all transfers of research material (Research Material) whether PHS is identified below as its Provider or Recipient.

Provider: *ModernaTX, Inc.*

Recipient: *National Institute of Allergy and Infectious Diseases, National Institutes of Health*

1. Provider agrees to transfer to Recipient's Investigator the following "Research Material":  
Sera from B/6 mice that have been vaccinated with Provider's investigational zika virus vaccine (5 placebo samples and 5 active samples). Proprietary Info
2. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. The Research Material will only be used for research purposes by Recipient's Investigator in his/her laboratory, for the Research Project described below, under suitable containment conditions. This Research Material will not be used for commercial purposes such as screening, production or sale, for which a commercialization license may be required. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.
  - a. Are the Research Materials of human origin?  
 Yes  No
  - b. If Yes in 2a, were Research Materials collected according to 45 CFR Part 46, "Protection of Human Subjects"?  
Yes Please provide Assurance Number:  
No
3. This Research Material will be used by Recipient's Investigator solely in connection with the following research project ("Research Project") described with specificity as follows (use an attachment page if necessary):  
  
The sera will be tested in a reporter virus particle (RVP) assay to understand the correlation with other commonly used assays for neutralizing titer in which the sera have already been tested. The RVP assay is more sensitive than plaque or focus reduction assays.
4. In addition to and not in lieu of any other confidentiality agreements between the Parties, either Party and its Affiliates ("Disclosing Party") may disclose Confidential Information (as defined below) to the other Party ("Receiving Party") during the term of this Agreement. For purposes of this Agreement, "Affiliate" means any corporation or other business entity controlled by, controlling or under common control with a Party at any time during the term of this Agreement; "control" means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock of at least fifty percent (50%) interest in the income of the corporation of

other business entity. Confidential Information disclosed pursuant to this Agreement shall be governed only by this Agreement and without regard for any other confidentiality agreements between the Parties. Neither Party, when acting as the Receiving Party, will, either during or for a period of **Proprietary Info**

**Proprietary** of this Agreement, (a) disclose to any third party the Disclosing Party's Confidential Information, or (b) use any Confidential Information of the Disclosing Party for any purpose other than the performance of the Research Project, without the prior written authorization of the Disclosing Party. For purposes of this paragraph 4, "Confidential Information" of Provider includes, without limitation, information concerning the Research Material and non-public technical, business and financial information relating to Provider and its Affiliates. Each Disclosing Party will use reasonable efforts to mark or designate Confidential Information provided in written or other tangible form as "CONFIDENTIAL" (or with a similar designation conveying confidentiality). Each Disclosing Party will use reasonable efforts to identify Confidential Information which is orally disclosed as "CONFIDENTIAL" at the time of disclosure, or in a writing marked as "CONFIDENTIAL" provided by the Disclosing Party within thirty (30) days of such disclosure.

Notwithstanding the above, failure to mark, identify or summarize information as "Confidential" shall not disqualify such information from constituting "Confidential Information" herein where such information would be reasonably expected to be treated in a confidential manner under the circumstances of disclosure. Receiving Party's obligations shall not extend to any part of the Confidential Information of a Disclosing Party: (v) that can be demonstrated to have been in the public domain or publicly known at the time of disclosure; (w) that can be demonstrated to have been in the Receiving Party's possession (as evidenced by written record) or that can be demonstrated to have been readily available to the Receiving Party from another source prior to the disclosure; (x) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by the Receiving Party; (y) that can be demonstrated as independently developed or acquired by Receiving Party without reference to or reliance upon such Confidential Information; or (z) that is required to be disclosed by law.

5. This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient's Investigator therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under her or his direct supervision without advance written approval of Provider. All data, information and results generated by Recipient from the Research Project (the "Results") shall be treated as Confidential Information until published pursuant to Section 7; provided that the Parties may use the Results for any internal purpose and Provider may disclose the Results and Reports (defined below) in connection with regulatory or patent filing, or in confidence to Provider's actual or potential investors who are not pharmaceutical, biotech, or other companies primarily engaged in the business of discovering, developing, manufacturing or the marketing of pharmaceutical products, or to Provider's bona fide third party collaborators provided that any third party collaborators **Proprietary Info**

**Proprietary Info**

**Proprietary** shall be approved in advance by the Recipient. Upon completion of the Research Project, or upon Provider's request, Recipient shall furnish a report ("Report") to Provider regarding the use of the Research Material, Results and the status of the Research Project. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed or three (3) years have elapsed, whichever occurs first, the Research Material will be disposed of as directed by Provider.

6. This Research Material is provided as a service to the research community. **IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties. No license is granted under this Agreement by either party to the other, either expressly or by implication, except for Recipient's right to use the Research Material solely for purposes of the Research Project.

7. Provider agrees that Recipient may publish the Results in peer-reviewed scientific journals or present those Results at academic symposia or similar professional meetings in accordance with the following provisions. Such public disclosure may be made only after Provider has had thirty (30) days to review the proposed disclosure to determine if it includes any Confidential Information or patentable invention, as defined under United States patent law. Recipient will comply with Provider's requests to remove its Confidential Information from any proposed disclosure and Provider will make a good faith effort to provide substitute nonconfidential information, if available, in the case that such information is necessary for a publication to

proceed: Proprietary Info

Proprietary Info

Proprietary Info In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's contribution of this Research Material unless

CoAK  
1/23/11

8.

Proprietary Info

Provider and Recipient recognize that inventorship will be determined under U.S. patent law. Proprietary Info

Proprietary Info

- 9. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.
- 10. This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.
- 11. This Agreement shall expire six (6) months from the date of last signature. Either party shall have the right to terminate this Agreement upon 30-day advance written notice to the other party. Notwithstanding such termination, the provisions of this Agreement shall survive termination other than with respect to Recipient's rights to continue the Research Project.

SIGNATURES BEGIN ON NEXT PAGE

**MATERIAL TRANSFER AGREEMENT  
SIGNATURE PAGE**

**FOR RECIPIENT:**

*Recipient's Investigator*

Barney Graham, MD, PhD  
Deputy Director, VRC

Date: \_\_\_\_\_

Mailing Address for Materials:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Tel: \_\_\_\_\_

Fax: \_\_\_\_\_

*Duly Authorized*

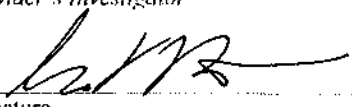
  
Carol Salata, PhD  
Senior Advisor for Technology Transfer, TTIPO,  
NIAID

Date: 1/23/17

Mailing Address for Notices:  
Technology Transfer and Intellectual Property Office  
National Institute of Allergy and Infectious Diseases  
5601 Fishers Lane, Suite 6D  
Bethesda, Maryland 20892-9804  
Courier: Rockville, Maryland 20852-9804

**FOR PROVIDER:**

*Provider's Investigator*

  
Signature

Scott Butler  
Printed Name and Title

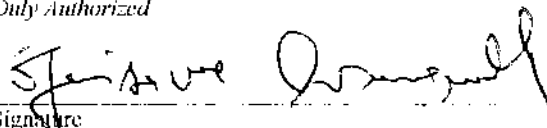
Date: 1/27/17

Mailing Address:

Valera  
500 Technology Square  
Cambridge, MA 02142

Tel: 781-434-8246 Fax: 617-649-3872

*Duly Authorized*

  
Signature

GIUSEPPE CIARAMELLA  
Printed Name and Title

Date: 1/27/17

Mailing Address for Notices:

Valera  
500 Tech. Sq.  
Cambridge, MA 02142

Tel: 617-209-5818 Fax: \_\_\_\_\_

## RESEARCH COLLABORATION AGREEMENT

This Research Collaboration Agreement ("Agreement") is between the National Institute of Allergy and Infectious Diseases ("NIAID"), which is a component of the National Institutes of Health ("NIH"), an agency of the U.S. Department of Health and Human Services, having offices located at 5601 Fishers Lane, Rockville, MD 20852, and ModernaTX, Inc. ("Moderna" or "Collaborator"), having a principal place of business at 320 Bent Street, Cambridge, MA 02141 and incorporated in the State of Delaware (collectively, the "Parties"). This Agreement is neither a funding agreement as defined in 35 U.S.C. § 201(b) nor a cooperative research and development agreement authorized under the Federal Technology Transfer Act of 1986, as amended, 15 U.S.C. §§ 3710a *et seq.* and Executive Order 12591 of April 10, 1987. NIAID enters into this Agreement pursuant to the authority of the Public Health Services Act of 1944, as amended (42 U.S.C. § 241).

### BACKGROUND

1. NIAID and Collaborator want to collaborate on a research project; and
2. NIAID and Collaborator want to transfer between the laboratories of their investigators, during the term of this Agreement, proprietary research materials required to conduct the research project.

### TERMS AND CONDITIONS

#### Article I DEFINITIONS

- 1.1 "Affiliate" means any corporation or other business entity controlled by, controlling, or under common control with Collaborator at any time during the term of this Agreement. For this purpose, "control" means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or at least fifty percent (50%) interest in the income of the corporation or other business entity.
- 1.2 "Confidential Information" includes scientific, business, or financial information pertaining to the Research Project (defined below) that is disclosed by Provider (defined below). Confidential Information does not include information that: (i) is in the public domain other than as a result of a disclosure by Recipient (defined below) or any of Recipient's representatives in violation of this Agreement; (ii) was in the possession of Recipient before disclosure by the Provider; (iii) is acquired by Recipient from a third party having no obligation of confidentiality to Provider; (iv) is hereafter independently developed by Recipient, without reference to Confidential Information received from Provider; or (v) Provider expressly authorizes Recipient to disclose.
- 1.3 "Invention" means any invention or discovery that is or may be patentable or protectable under applicable laws.
- 1.4 "Investigator" means the principal researcher designated by a Party to direct the Research Project.
- 1.5 "Material" means Original Material, Progeny, and any material created by Recipient that constitutes an unmodified functional subunit of or product expressed by Original Material including but not limited to subclones of unmodified cell lines, purified or fractionated subsets, proteins expressed by DNA/RNA, or monoclonal antibodies secreted by a hybridoma cell line.
- 1.6 "Original Material" means a material provided by one of the Parties to be used in the Research Project.
- 1.7 "Progeny" means unmodified descendent from Material, such as virus from virus, cell from cell, or organism from organism.



- 1.8 “**Provider**” means the Party that provides Original Material or discloses Confidential Information to the other Party under this Agreement. “Provider” includes, with respect to Collaborator, Affiliates of Collaborator.
- 1.9 “**Recipient**” means the Party that receives Original Material or Confidential Information from the other Party under this Agreement. “Recipient” includes, with respect to Collaborator, Affiliates of Collaborator.
- 1.10 “**Research Project**” means the collaborative research described in Appendix A.

## **Article 2 COLLABORATIVE RESEARCH**

- 2.1 NIAID and Collaborator agree to collaborate on the Research Project. The Investigators for NIAID will be Barney Graham, MD, PhD, John Mascola, MD, Ted Pierson, PhD and the Investigator for Collaborator will be Scott Butler, PhD.
- 2.2 Nothing in this Agreement will be construed to limit the freedom of either Party from engaging in similar research with other parties, providing the research does not create a conflict with the Parties’ obligations under this Agreement, especially with regard to Article 3.
- 2.3 The Parties recognize that the Research Project describes the collaborative research to be conducted under this Agreement and that the goals set forth in Appendix A are good faith guidelines. If events occur that require substantial modification of the Research Project, the Parties may amend Appendix A according to Paragraph 6.9 of this Agreement.

## **Article 3 CONFIDENTIALITY; PUBLICATIONS**

### **3.1 Confidential Information**

- 3.1.1 Either Party may disclose or receive Confidential Information under this Agreement.
- 3.1.2 The Disclosing Party shall use reasonable efforts to (a) mark Confidential Information in any written document, memorandum, report, correspondence, drawing, or other tangible material as “Confidential Information” or “Confidential” and (b) reduce oral disclosures of Confidential Information, or disclosures through observation of Confidential Information, to a writing marked “Confidential Information” or “Confidential” within 30 days after disclosure to be considered Confidential Information. Notwithstanding the above, failure to mark information as “Confidential” will not disqualify that information from constituting “Confidential Information” under this Agreement if a reasonable person would consider such information to be confidential based on the nature of such information and the circumstances of disclosure.
- 3.1.3 Recipient will maintain Confidential Information in confidence for a period of five (5) years from the Effective Date and will protect Confidential Information with the same degree of care as Recipient uses to protect its own Confidential Information but in no event less than a reasonable standard of care.
- 3.1.4 Recipient may disclose Confidential Information to its and its Affiliates’ employees, consultants, or contractors to whom it is necessary to disclose this information for the purpose of the Research Project; Recipient may make these disclosures only under terms at least as restrictive as those specified in this Agreement. Recipient agrees that disclosure of Confidential Information may not be made to any party not listed herein unless Provider grants prior written approval to Recipient.
- 3.1.5 Recipient may disclose Provider’s Confidential Information if required to do so by law, regulation, or court order. If Recipient, or anyone to whom it discloses Confidential

Information in accordance with Article 3, becomes legally required to disclose any Confidential Information, Recipient will provide timely notice to Provider and, to the extent practicable, consult with Provider prior to any disclosure.

3.1.6 Either Party may disclose the Abstract of the Research Project (in Appendix A) to the public.

3.1.7 Proprietary Info

### 3.2 Publications; Press Releases

#### 3.2.1 Publications

3.2.1.1 In addition to the specific goals of the Research Project, the Parties view dissemination of research findings, both by publication and oral presentation, as an essential objective of the Research Project. Authorship will be decided according to commonly accepted conventions for scientific publications.

3.2.1.2 The Parties are encouraged to make publicly available the Results of the Research Project. Proprietary Info

Proprietary Info

Proprietary Info

Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about the Results or any Invention made in the course of the Research Project, the other Party will have 30 days to review proposed manuscripts and 7 days to review proposed abstracts to ensure that Confidential Information and/or Inventions are protected. Either Party will have the right to remove any Confidential Information of that Party and its Affiliates from any such proposed publication or other public disclosure and will make a good faith effort to provide substitute information, if available, in the case that such information is necessary for the proposed publication to proceed. Proprietary Info

Proprietary Info

In addition, either Party may request in writing that the proposed publication or other disclosure be delayed for up to 30 additional days as necessary to file a patent application.

#### 3.2.2 Press Releases

. Press releases that reference or rely upon the research under this Agreement will be made available to the other Party for review and comment at least 7 days prior to publication.

## Article 4 INVENTIONS; DATA

### 4.1 Inventions

4.1.1 The Parties acknowledge the possibility that Inventions may be made in the performance of the Research Project. Ownership of such Inventions will follow inventorship, which will be determined in accordance with applicable U.S. laws and regulations.

4.1.2 Inventions made in the performance of the Research Project will be owned by the Party employing the inventor or inventors. Inventions made in the performance of the Research

Project that are invented jointly by employees of both Parties will be owned jointly. For clarity, references to "employee(s)" of a Party in this Section 4.1.2 shall include employees and agents of such Party and its Affiliates that are conducting or performing activities as a part of the Research Project.

- 4.1.3 Each Party will report to the other Party, in writing, all Inventions made in the performance of the Research Project no later than three (3) months from the time the invention is disclosed to a Party by its Investigator. The reports will be written in sufficient detail to determine inventorship and will be treated as Confidential Information in accordance with Article 3. The Parties will confer with each other regarding a patent filing strategy for jointly made Inventions. If either Party files a patent application on a jointly made Invention, then the filing Party will include a statement in the patent application that clearly identifies the Parties and states that the Invention was made jointly under this Agreement.

- 4.1.4 Proprietary Info

#### 4.2 Data

Upon the request of the other Party, each Party will disclose to the other Party a summary of all data, information and results generated from the use of the Material(s) in the performance of the Research Project under this Agreement ("Results"). The Parties may use the Results for their own internal purposes, but shall otherwise maintain the Results in confidence until published in accordance with Article 3.2; provided that the Parties shall have the right to disclose the Results prior to publication in connection with any regulatory or patent filing. Further, Collaborator shall have the right to disclose the Results prior to publication to (a) Collaborator's actual or potential investors who are not pharmaceutical, biotech, or other companies primarily engaged in the business of discovering, developing, manufacturing or the marketing of pharmaceutical product, (b) Collaborator's bona fide third party collaborators as of the Effective Date, Proprietary

Proprietary Info

Proprietary Info

and (c) with prior written consent of NIAID, bona fide collaborators of Collaborator arising after the Effective Date, provided that in each case ((a)-(c)) such actual or potential investors and third party collaborators are bound by written agreement to treat the Results as confidential and such written agreements contain confidentiality obligations at least as restrictive as those herein.

### Article 5 THE TRANSFER AND USE OF MATERIAL

#### 5.1 Mechanics of Transfer

Either Party may provide or receive Original Material under this Agreement. Provider will send Original Material to Recipient with a cover letter as described in Appendix B. The letter will refer to this Agreement and identify Original Material. If either Party transfers to the other Party a material not listed in Appendix A, the Parties will amend this Agreement to include the additional material.

#### 5.2 Conditions of Use

- 5.2.1 RECIPIENT WILL NOT USE MATERIAL IN RESEARCH INVOLVING HUMAN SUBJECTS.

- 5.2.2 Recipient's Investigator will use Material solely in connection with the Research Project in the Investigator's laboratory. If Recipient wants to use Material for commercial purposes, Recipient agrees to first obtain the appropriate commercial use or commercialization license from Provider.
- 5.2.3 Recipient agrees that Recipient's Investigator will retain control over Material and further agrees that Recipient's Investigator will not transfer Material to people not under the Investigator's direct supervision without advance written approval of Provider.
- 5.2.4 Proprietary Info
- 5.2.5 Recipient will use Material in compliance with all applicable laws, regulations and policies.
- 5.2.6 Nothing in this Agreement shall restrict Provider from using or distributing its Original Materials.
- 5.2.7 Upon termination of this Agreement, Recipient agrees that Recipient's Investigator will return any and all remaining Original Material unless Provider gives Recipient's Investigator directions for disposing of Original Material by another means.
- 5.2.8 Nothing in this Agreement will be construed as conferring on Recipient any implied license to Material, or option to license Material, any technology, or any patent or patent application owned by Provider and will not create any obligation, by implication or otherwise, of either Party to enter into any further agreement with the other Party.

## **Article 6 TERMINATION AND GOVERNANCE**

### **6.1 Effective Date**

This Agreement will be effective on the date of the last authorized signature below.

### **6.2 Term and Termination**

- 6.2.1. The Parties agree that this Agreement will be effective for one (1) year from the date of the last authorized signature below and may be extended as mutually agreed by the Parties in a written amendment to this Agreement.
- 6.2.2 This Agreement will terminate immediately upon the mutual agreement of the Parties in writing.
- 6.2.3 This Agreement will terminate in 30 days after either Party receives written notice of the other Party's desire to terminate this Agreement.

### **6.3 Representations, Warranties, and Liability**

- 6.3.1 Material is understood to be experimental in nature and may have hazardous properties. ORIGINAL MATERIAL IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of Material will not infringe any patent or other proprietary rights of third parties.
- 6.3.2 No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement. Each Party will be liable for any loss, claim, damage, or liability that the Party incurs as a result of its activities under this Agreement, except

that NIAID, as an agency of the U.S. Government, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. §§ 2671 *et seq.*

**6.4 Assignment**

Neither this Agreement nor any rights or obligations of either Party hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party. Propriet

Proprietary Info

Proprietary Info

This Agreement will be binding upon the Parties and their respective successors and permitted assigns.

**6.5 Non-endorsement**

By entering into this Agreement, NIAID does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to this Agreement, by Collaborator, its successors, permitted assigns, or licensees. Collaborator will not in any way state or imply that this Agreement is an endorsement of any such product or service by the U.S. Government or any of its organizational units or employees.

**6.6 Survivability**

Articles 3, 4, 5.2, 6.3, 6.5, 6.6 and 6.8 will survive expiration or earlier termination of this Agreement.

**6.7 Severability**

The illegality or invalidity of any provisions of this Agreement will not impair, affect, or invalidate the other provisions of this Agreement.

**6.8 Governing Law**

The construction, validity, performance, and effect of this Agreement will be governed by federal law as applied by the federal courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement.

**6.9 Entire Agreement**

This Agreement, together with all appendices, constitutes the entire agreement between the Parties and supersedes any prior or contemporaneous oral or written agreements or communications between them with respect to the subject matter hereof. This Agreement may be amended only by written instrument signed by authorized representatives of NIAID and Collaborator.

**6.10 Notices**

All notices pertaining to or required by this Agreement shall be in writing, shall be signed by an authorized representative and shall be delivered to the addresses indicated on the signature page for each Party.

**SIGNATURES BEGIN ON THE NEXT PAGE**

FOR NIAID:

*Vince Feliccia*

Vince Feliccia, PhD, JD  
Branch Chief, TTIPO, NIAID

2/3/2017  
Date

Mailing Address for Notices:

ATTN: COLLABORATION AGREEMENT  
TECHNOLOGY TRANSFER AND INTELLECTUAL PROPERTY OFFICE, NIAID  
Suite 6D, MSC 9804, 5601 Fishers Lane  
Rockville, MD 20852  
Tel: 301-496-2644 / Fax: 240-627-3117

Acknowledgment by NIAID's Investigators:

*Barney Graham*

Barney Graham, MD, PhD  
Deputy Director, VRC, NIAID

21 Feb 2017  
Date

*John Mascola*

John Mascola, MD  
Director, VRC, NIAID

21 FEB 2017  
Date

Ted Pierson, MD  
Chief, Viral Pathogenesis Section  
Laboratory of Viral Diseases, NIAID

\_\_\_\_\_  
Date

FOR ModernaTX:

*Giuseppe Ciaramella*

Printed name GIUSEPPE CIARAMELLA  
Title CHIEF SCIENTIFIC OFFICER, VALERA LLC

2/14/2017  
Date

Mailing Address for Notices:  
ModernaTX, Inc.  
320 Bent Street  
Cambridge, MA 02141

Tel: \_\_\_\_\_

Fax: \_\_\_\_\_

Acknowledgment by Moderna's Investigator:

*Scott Butler*

Scott Butler, PhD  
Director of Virology and Project Leader  
Valera LLC, an Affiliate of ModernaTX, Inc.

2/14/2017  
Date

## APPENDIX A

### Research Project

#### Evaluation of an mRNA vaccine for Zika virus

##### I. Abstract of the Research Project – for Public Release

EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION, RELEASE THIS ABSTRACT TO THE PUBLIC.

NIAID and Moderna will collaborate to evaluate immunogenicity of an mRNA vaccine for Zika virus in animal models.

##### II. Goal(s) of Project

*The goals of this project are to:*

- Evaluate the immunogenicity of a Zika virus mRNA vaccine [Proprietary Info]
- Determine efficacy of the mRNA vaccine [Proprietary Info]

##### III. Background

Zika virus (ZIKV) is a major public health threat for which there are currently no licensed vaccines or anti-viral treatments. Infection with ZIKV, an enveloped, positive-stranded RNA virus from the Flaviviridae family, can cause a symptomatic infection characterized by fever, rash, arthralgia, headache, malaise, muscle pain and periorbital pain. Importantly, contraction of ZIKV during pregnancy has been associated with birth defects, most notably microcephaly. The ZIKV outbreak in Brazil in 2015 and subsequent association with congenital disease led to a declaration of a global health emergency. Therefore, accelerated vaccine development is a high priority and rapidly acquiring information on immunogenicity and efficacy of vaccine candidates is desirable. In this collaborative project, we will evaluate immunogenicity and efficacy of a mRNA vaccine against ZIKV [Proprietary Info]

The Vaccine Research Center, NIAID (“VRC/NIAID”) has extensive experience with the development of vaccines against infectious diseases. In particular, VRC/NIAID has previously developed a vaccine against West Nile virus, a flavivirus related to Zika Virus and has evaluated two DNA vaccine candidates for ZIKV. Additionally, NIAID has also developed diagnostic assays to evaluate immunogenicity of vaccine candidates and antibody neutralization.

Moderna has prior experience using mRNA as a vaccine platform, including for development of two vaccines that are currently being evaluated in Phase I clinical trials, and they have developed a proprietary mRNA vaccine for ZIKV.

The purpose of these studies is to evaluate immunogenicity and efficacy of a mRNA vaccine for ZIKV [Proprietary Info]

**IV. Original Materials Contributed by the Parties**

- i. **VRC, NIAID Original Material:**
  - Zika virus challenge stock
  - Reagents for serological assays
  
- ii. **Collaborator Original Material:**
  - Control mRNA vaccine
  - Moderna's proprietary Zika Virus mRNA vaccine

**V. Respective Contributions of the Parties**

**VRC, NIAID will:**

- Proprietary Info
- 

**Collaborator will:**

- Proprietary Info
- 

**VI. Experimental Plan**

- 1. Proprietary Info
  - 2. Proprietary Info
- 

The Parties will work together to plan these experiments and discuss the results.



APPENDIX B

**Sample Material Transfer Cover Letter**

*A sample letter follows.*

Date

Provider Organization Name  
Provider Organization Address  
Tel:  
Fax:

Recipient PI  
Recipient Organization  
Recipient Organization Address

**RE: TRANSFER OF MATERIAL(S) UNDER COLLABORATION AGREEMENT BETWEEN NIAID AND  
[NAME OF COLLABORATOR] DATED [MONTH/YEAR]**

**DEAR DR. [NAME OF NIAID PI OR COLLABORATOR PI]:**

The [National Institute of Allergy and Infectious Diseases (NIAID) or Collaborator] is pleased to provide you with the following material(s): [Describe material(s)]. The material(s) developed by [insert name], are being shipped to you by [NIAID/ Collaborator].

The material(s) may only be used for research conducted between NIAID and [Collaborator] under the Collaboration Agreement referenced above. In addition, you understand that any remaining material(s) will be returned to [NIAID/ Collaborator] or disposed of according to the written instructions of [NIAID/ Collaborator] when the Collaboration Agreement expires, unless [NIAID/ Collaborator] obtains permission from [NIAID/ Collaborator] to continue using the materials.

Please acknowledge receipt of the material(s) by signing below. At your earliest convenience, please fax a copy of this letter to your technology transfer office at [NIAID/ Collaborator].

Sincerely,

NIAID/ Collaborator [Provider]  
Title  
cc:

Acknowledged by NIAID/ Collaborator PI [Recipient]

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name and Title

## *Confidential Disclosure Agreement*

In order to protect confidential information relating to research, development, business plans, and other technology, which may be disclosed between them, the National Institute of Allergy and Infectious Diseases, a component of the National Institutes of Health, an agency of the U.S. Department of Health and Human Services (“NIAID, NIH”), and Moderna TX, Inc. and the following Affiliates of ModernaTX, Inc. (“Affiliate” means any corporation or other business entity controlled by, controlling, or under common control with Collaborator at any time during the term of this Agreement. For this purpose, “control” means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or at least fifty percent (50%) interest in the income of the corporation or other business entity):

**Proprietary Info** (collectively, the “Collaborator”) (collectively the “Parties” and individually a “Party”), intending to be legally bound as of the date of the last authorized signature hereto (“Effective Date”), agree that:

1. A Party (“Disclosing Party”) may disclose information to the other (“Receiving Party”) for the purpose of assessing their interest in a research collaboration (the “Purpose”). The Disclosing Parties are: **NIAID, NIH and Collaborator**. The Receiving Parties are: **NIAID, NIH and Collaborator**.

2. The Parties’ representatives for disclosing or receiving information (if known):

For NIAID, NIH: Dr. Jeffrey Cohen

For Collaborator: Giuseppe Ciaramella,  
Leslie Johnson,  
Shinu John, and other employees of the Collaborator as needed to fulfill the Purpose.

3. The information disclosed under this Agreement (“Confidential Information”) is described as:

NIAID, NIH may disclose results of in vitro and animal model studies of NIAID, NIH’s candidate vaccines against Epstein Barr Virus and Herpes Simplex Virus

Collaborator may disclose non-public technical, business and financial information, including third party information for which Collaborator has an obligation to maintain as confidential, relating to the research, design, manufacture, development, and commercialization of messenger RNA (mRNA) and the use of mRNA for the treatment and prevention of disease.

4. The Receiving Party shall use Confidential Information of the Disclosing Party only for the Purpose, and for no other purpose. The Receiving Party will not disclose the Confidential Information of the Disclosing Party to any person except its employees, consultants and contractors, to whom it is necessary to disclose the Confidential Information for the Purpose described above, and any such disclosures shall be under terms at least as restrictive as those specified herein. Any of the persons mentioned above who are given access to the Confidential Information shall be informed of this Agreement. The Receiving Party shall protect the Confidential Information by using the same degree of care, but no less than a reasonable degree of care, as the Receiving Party uses to protect its own confidential information.

5. The Receiving Party’s duties under this Agreement shall apply only to Confidential Information in any written document, memorandum, report, correspondence, drawing, or other tangible material, or computer software or program, developed or prepared by the Disclosing Party or any of its representatives that has been clearly marked “Confidential” by the Disclosing Party. Oral disclosures must be reduced to

writing (this may be by summary email or other electronic communication) and marked "Confidential" within thirty (30) days after disclosure to be considered Confidential Information.

6. Notwithstanding any other provision of this Agreement, Confidential Information shall not include any item of information, data, patent or idea that: (a) is within the public domain prior to the time of the disclosure by the Disclosing Party to the Receiving Party or thereafter becomes within the public domain other than as a result of disclosure by the Receiving Party or any of its representatives in violation of this Agreement; (b) was, on or before the date of disclosure in the possession of the Receiving Party; (c) is acquired by the Receiving Party from a third party not under an obligation of confidentiality; (d) is hereafter independently developed by the Receiving Party, without use of or reference to the Confidential Information received from the Disclosing Party; or (e) the Disclosing Party expressly authorizes in writing the Receiving Party to disclose.

7. At the request of the Disclosing Party, the Receiving Party agrees to return or destroy all Confidential Information received from the Disclosing Party except that the Receiving Party may retain in its confidential files one (1) copy of written Confidential Information for record purposes only.

8. If the Receiving Party, or anyone to whom it discloses the Confidential Information in accordance with Paragraph 4, becomes legally required to disclose any of the Confidential Information, the Receiving Party shall, to the extent practicable, provide the Disclosing Party with timely notice and, to the extent practicable, consult with the Disclosing Party prior to any disclosure.

9. This Agreement is to be made under and shall be construed in accordance with Federal laws as applied by the Federal Courts in the District of Columbia, and constitutes the entire understanding between the Parties with respect to the subject matter hereof and merges any and all prior agreements, understandings and representations. The Agreement may not be superseded, amended or modified except by written agreement between the Parties. This Agreement will control the disclosure of Confidential Information for a disclosure period beginning on the Effective Date and expiring one (1) year thereafter, and the remaining terms and conditions of this Agreement will expire four (4) years from the Effective Date. Either party may terminate this Agreement upon thirty (30) days written notice to the other Party.

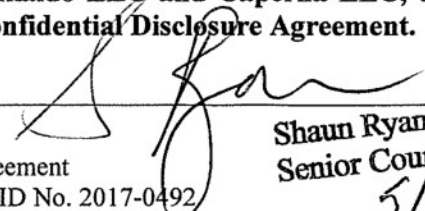
10. This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument. A facsimile, scanned electronic signature or certified electronic signature shall be as effective as an original signature.

ModernaTX, Inc.  
320 Bent Street  
Cambridge, MA 02141

**National Institute of Allergy and Infectious  
Diseases  
Technology Transfer and Intellectual  
Property Office  
Suite 6D, MSC 9804  
5601 Fishers Lane  
Rockville, MD 20852**

Authorized Signature:

**I, the undersigned, hereby warrant that I have the authority to legally bind ModernaTX Inc. and its Affiliates, Valera LLC, Elpidera LLC, Onkaido LLC and Caperna LLC, under this Confidential Disclosure Agreement.**

  
\_\_\_\_\_  
**Shaun Ryan  
Senior Counsel**  
5/23/17

Agreement  
NIAID No. 2017-0492

Authorized Signature:

\_\_\_\_\_  
Maryann T. Puglielli, Ph.D., J.D.,  
Lead TDS, TTIPO, NIAID, NIH

Date: May 30, 2017

Confidential Disclosure  
Page 2 of 3  
modified June 16, 2014

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Acknowledged by NIAID Representative(s)  
Disclosing/Receiving Confidential Information:

\_\_\_\_\_  
Jeffrey I. Cohen, M.D.,  
Chief, Laboratory of Infectious Diseases, NIAID,  
NIH

Date: \_\_\_\_\_

## MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement (“MTA”) has been adopted for use by the National Institute of Allergy and Infectious Diseases (“NIAID”), an institute at the National Institutes of Health, which is part of the Department of Health and Human Services, an agency of the United States Government (“Provider”) in transfers of research material to for-profit institutions for internal research.

Recipient: **ModernaTX, Inc.**, having offices at 500 Technology Square Cambridge, MA 02139, created and operating under the laws of Delaware.

1. Provider agrees to transfer to Recipient’s Investigator the following material(s), including known functional components or subunits and unmodified descendants thereof (“Research Material”):

Name/Description	Reference
<u>RVP #1</u> : pZIKV-H/PF/2013-CprME; a DNA expression construct expressing C-prM-E structural genes of ZIKV strain H/PF2013	Dowd <i>et al.</i> , Cell Rep. 2016 Aug 9; 16(6): 1485–1491. (PMID: 27481466)
<u>RVP#2</u> : pDENV1-WestPac-CprME; DNA expression construct expressing C-prM-E structural genes of DENV strain Western Pacific	Ansarah-Sobrinho <i>et al.</i> , Virology. 2008 Nov 10; 381(1):67-74. (PMID: 18801552)
<u>RVP#3</u> : pDENV2-16681-CprME; a DNA expression construct expressing C-prM-E structural genes of DENV strain 16681	Ansarah-Sobrinho <i>et al.</i> , Virology. 2008 Nov 10; 381(1):67-74. (PMID: 18801552)
pFurin; a DNA expression construct expressing human furin protease	Davis <i>et al.</i> , J Virol. 2006 Feb; 80(3):1290-301. (PMID: 16415006)
<u>Replicon#1</u> : pWNVII-Rep-G/Z; a WNV lineage II replicon expressing GFP and zeocin resistance	Pierson <i>et al.</i> , Virology. 2006 Mar 1;346(1):53-65. (PMID: 16325883)
<u>Replicon#2</u> : pWNVII-Rep-Ren-IB; a WNV lineage II replicon expressing Renilla luciferase and blasticidin resistance	Pierson <i>et al.</i> , Virology. 2006 Mar 1;346(1):53-65. (PMID: 16325883)

2. **THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS.** The Research Material will only be used for commercial research purposes by Recipient’s Investigator in his/her laboratory, for the research project described below, under suitable containment conditions. **The Research Material will not be used in any product offered for sale or processes for the manufacture thereof, including quality control procedures, or in commercial services for which a commercialization license from the National Institutes of Health (“NIH”) is required. The Research Material and methods of using the Research Material are the subject of U.S. and foreign patent applications. Please contact the TTPO, NIAID, if information is desired concerning the present status of this invention or how to license the Research Material and/or patents covering the Research Material. The HHS Reference number to these inventions is E-181-2016/0.**

Recipient agrees to comply with all laws, rules and regulations applicable to the Research Project and the handling of the Research Material.

- a. Is the Research Material of human origin?

Yes       No

- b. If Yes in 2a, was Research Material collected according to 45 C.F.R. Part 46, "Protection of Human Subjects"?

Yes      Please provide Assurance Number: \_\_\_\_\_  
 No

3. This Research Material will be used by Recipient's Investigator solely in connection with the following research project ("Research Project") described with specificity as follows:

The Recipient will use the Research Material to perform neutralizing titer assays **Proprietary Info**  
**Proprietary Info** as an immunogenicity readout for several *in vivo* studies the Recipient will run in support of its vaccine programs **Proprietary Info**

4. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's contribution of this Research Material unless requested otherwise. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of Provider's written information about this Research Material that is stamped "CONFIDENTIAL," except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from Provider to Recipient shall be identified as being CONFIDENTIAL by notice delivered to Recipient within ten (10) days after the date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if Provider has given CONFIDENTIAL information to Recipient such public disclosure may be made only after Provider has had thirty (30) days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information, except when a shortened time period under court order or the Freedom of Information Act pertains.
5. This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient therefore agrees that Recipient's Investigator will retain control over this Research Material and further agrees that Recipient's Investigator will not transfer the Research Material to other people not under her or his supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. **When the Research Project is completed, or this MTA is terminated, or nine (9) months have elapsed, whichever occurs first, the Research Material will be returned to the Provider or disposed of as directed by Provider. If the Recipient depletes its supply of Research Material or destroys the Research Material pursuant to this Paragraph 4 Recipient will so notify Provider in writing.**
6. This Research Material is provided as a service to the research community. **IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.
7. Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. Recipient agrees not to claim, infer, or imply governmental endorsement of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s). Each Party shall be responsible for its own negligence under this MTA. Unless prohibited by law from doing so, recipient agrees to hold the United States Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of any third party claim or suit in connection with the Recipient's use for any purpose of the Research Material, except to the extent that any such liability, demand, damage, expense or loss is attributable to Provider's negligence.
8. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

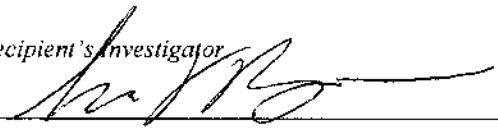
9. This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.
10. In the event that Recipient wishes to use the Research Material for commercial purposes other than the commercial research described in Paragraph 3 above, Recipient agrees to first obtain from NIH the appropriate commercial use or commercialization license.
11. Either Provider or Recipient may unilaterally terminate this MTA at any time by giving written notice to the other Party at least thirty (30) days prior to the desired termination date.
12. The provisions of Paragraphs 4, 5, 7, 9, 10 and 12 of this MTA will survive expiration or termination.
13. This MTA may be executed in counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument. A facsimile, scanned electronic signature or certified electronic signature shall be as effective as an original signature.
14. The Research Material will be used for the Research Project described in Article 3 only. The Research Material will not be used in research projects:
  - (a) involving collaboration with another for-profit organization;
  - (b) sponsored or funded by another for-profit organization;
  - (c) in which Recipient or Recipient's Investigator is obligated to assign inventions containing the Research Material or offer an exclusive license to inventions containing the Research Material to an organization other than Recipient or a contractor of Recipient that manages Recipient's inventions on behalf of Recipient; or
  - (d) in which Recipient or Recipient's Investigator is obligated to receive permission from an organization other than Recipient before publicly disclosing results of research involving the Research Material.

**NOTE:** If Recipient wishes to use the Research Material in a research project that is forbidden above, Recipient should contact the Technology Transfer and Intellectual Property Office (TTIPO), National Institute of Allergy and Infectious Diseases (NIAID), to discuss whether permission to use the Research Material in such project can be obtained.

SIGNATURES BEGIN ON NEXT PAGE

**MATERIAL TRANSFER AGREEMENT  
SIGNATURE PAGE**

**FOR RECIPIENT:**


*Recipient's Investigator*  
  
Signature

Scott Butler, PhD  
Director of Virology & Project Leader

Date: 9/18/2017

Mailing Address for Materials:  
Moderna  
500 Technology Square  
Cambridge, MA 02139  
Attn: Brooke Bollman

Tel: (781) 434-8246  
Email: Scott.butler@valeratx.com

*Duly Authorized*  
  
Signature

Giuseppe Ciaramella  
Printed Name and Title

Date: SEP 18, 2017

Mailing Address for Notices:  
Moderna  
500 Technology Square  
Cambridge, MA 02139  
Tel: 617-209-5818 Fax:

**FOR PROVIDER:**

*Provider's Investigator*  
\_\_\_\_\_  
Theodore Pierson, Ph.D.  
Chief, Viral Pathogenesis Section  
Laboratory of Viral Diseases  
NIAID

Date: \_\_\_\_\_

Mailing Address:

Bldg 33 RM 2E19A2  
33 North Drive  
Bethesda, MD 20892

Tel: 301/451-7977 Fax: 301/451-7978

*Duly Authorized*  
Christopher M. Kornak -5  
Digital Signature of Christopher M. Kornak -5  
DN: cn=Chris Kornak, o=NIAID, ou=NIH, email=cmkornak@niaid.nih.gov, c=US  
Date: 2017.09.06 13:44:18 -0400  
Chris Kornak, J.D., M.S.  
Lead TTPS, Technology Transfer and Intellectual  
Property Office  
NIAID

09-06-2017

Date: \_\_\_\_\_

Mailing Address for Notices:

TECHNOLOGY TRANSFER AND INTELLECTUAL  
PROPERTY OFFICE  
NIAID, NIH  
Suite 6D, MSC 9804  
5601 Fishers Lane  
Rockville, MD 20852  
301-496-2644 (Office)

Tel: 301/496-2644 Fax: 301/402-7123



**AMENDMENT NUMBER ONE TO  
MATERIAL TRANSFER AGREEMENT**

This Amendment Number One (the "First Amendment") to the Material Transfer Agreement ("MTA")(NIAID Reference Number 2017-0993), having an effective date of September 18, 2017 is entered into as of the date of last authorized signature hereto (the "First Amendment Effective Date") and made by and between National Institute of Allergy and Infectious Diseases, National Institutes of Health, with its principal place of business at 5601 Fishers Lane, Suite 6D, MSC 9804, Rockville, MD 20852 ("Provider") and ModernaTX, Inc., having offices at 200 Technology Square Cambridge, MA 02139, created and operating under the laws of Delaware ("Recipient"). Each of Provider and Recipient may be referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, Provider and Recipient desire that the MTA be amended a first time as set forth below in order to modify the scope of the MTA Research Project Proprietary Info

Proprietary Info

Proprietary Info and

WHEREAS, the Parties have been operating under the MTA and desire to extend the term of MTA-FP 2017-0993 by one (1) month to July 18, 2018 while Company and NIAID conclude negotiations/finalization of License Agreement A-261-2018 and corresponding MTA-FP 2018-0664; and

WHEREAS, the Parties desire to amend the MTA as set forth in this First Amendment.

NOW, THEREFORE, the Parties hereby agree as follows:

1. Unless otherwise defined herein, capitalized terms used in this First Amendment have the meanings assigned thereto in the MTA.
2. This First Amendment may be signed by each Party separately on different signature pages, and each document when fully signed by a Party and delivered shall constitute an original instrument, and all such multiple signed documents shall constitute one and the same instrument. This First Amendment shall be effective as of the date of the final authorized signature hereto, the First Amendment Effective Date. Execution by the Parties shall be by original signature, electronic signature, or copy of signature received via portable document format (PDF) and an electronic signature or a PDF signature shall be deemed to be and shall be as effective as an original signature.
3. The description of the Research Project in paragraph 3 of the MTA is hereby deleted and replaced by the following:

**The Recipient's use of the Research Material will be confined solely to the scope of "Zika virus vaccine development" as limited to and defined by the HHS0100201600029C BARDA-funded Zika virus vaccine development award.**

4. Paragraph 5 of the MTA is hereby deleted and replaced with the following:

This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient therefore agrees that Recipient's Investigator will retain control over this Research Material and further agrees that Recipient's Investigator will not transfer the Research Material to other people not under her or his supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. **When the Research Project is completed, or this MTA is terminated, or on July 18, 2018, whichever occurs first, the Research Material will be destroyed by the Recipient. If the Recipient depletes its supply of Research Material or destroys the Research Material pursuant to this Paragraph 5 Recipient will so notify Provider in writing.**

5. Except as amended herein, all other terms and conditions of the MTA remain in full force and effect.

The Parties hereby accept and agree to the terms and conditions of this First Amendment.

**SIGNATURES BEGIN ON NEXT PAGE**

IN WITNESS WHEREOF, the authorized Parties hereto have caused this First Amendment to be duly executed and to be effective as of the First Amendment Effective Date.

**National Institute of Allergy and Infectious Diseases, National Institutes of Health ("Provider"):**

Benjamin E. Hurley - Digitally signed by Benjamin E.  
Hurley-S  
S Date: 2018.06.15 10:25:14 -04'00'

---

Benjamin Hurley  
TTPS, TTIPO, NIAID, NIH

Date: 15 June 2018

**ModernaTX, Inc. ("Recipient"):**

*Daphne M. Van de Meerssche*  
Name *Daphne M. Van de Meerssche*  
Title *Counsel*

Date: June 18, 2018

Read & Understood by Recipient Investigator

*Kapil Bahl*  
Kapil Bahl, Ph.D.  
Senior Scientist, ModernaTX, Inc.

Date: June 18, 2018

**AMENDMENT NUMBER TWO TO  
MATERIAL TRANSFER AGREEMENT**

This Amendment Number Two (the "Second Amendment") to the Material Transfer Agreement ("MTA")(NIAID Reference Number 2017-0993), having an effective date of September 18, 2017 is entered into as of the date of last authorized signature hereto (the "Second Amendment Effective Date") and made by and between National Institute of Allergy and Infectious Diseases, National Institutes of Health, with its principal place of business at 5601 Fishers Lane, Suite 6D, MSC 9804, Rockville, MD 20852 ("Provider") and ModernaTX, Inc., having offices at 200 Technology Square Cambridge, MA 02139, created and operating under the laws of Delaware ("Recipient"). Each of Provider and Recipient may be referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, Provider and Recipient desire that the MTA be amended a second time as set forth below in order to modify the scope of the MTA Research Project Proprietary Info

Proprietary Info  
Proprietary Info and

WHEREAS, the Parties have been operating under the MTA and desire to extend the term of MTA-FP 2017-0993 by two (2) months to August 18, 2018 while Company and NIAID conclude negotiations/finalization of License Agreement A-261-2018 and corresponding MTA-FP 2018-0664; and

WHEREAS, the Parties desire to amend the MTA as set forth in this Second Amendment.

NOW, THEREFORE, the Parties hereby agree as follows:

1. Unless otherwise defined herein, capitalized terms used in this Second Amendment have the meanings assigned thereto in the MTA.
2. This Second Amendment may be signed by each Party separately on different signature pages, and each document when fully signed by a Party and delivered shall constitute an original instrument, and all such multiple signed documents shall constitute one and the same instrument. This Second Amendment shall be effective as of the date of the final authorized signature hereto, the Second Amendment Effective Date. Execution by the Parties shall be by original signature, electronic signature, or copy of signature received via portable document format (PDF) and an electronic signature or a PDF signature shall be deemed to be and shall be as effective as an original signature.
3. The description of the Research Project in paragraph 3 of the MTA is hereby deleted and replaced by the following:  

**The Recipient's use of the Research Material will be confined solely to the scope of "Zika virus vaccine development" as limited to and defined by the HHS0100201600029C BARDA-funded Zika virus vaccine development award.**
4. Paragraph 5 of the MTA is hereby deleted and replaced with the following:

This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient therefore agrees that Recipient's Investigator will retain control over this Research Material and further agrees that Recipient's Investigator will not transfer the Research Material to other people not under her or his supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. **When the Research Project is completed, or this MTA is terminated, or on August 18, 2018, whichever occurs first, the Research Material will be destroyed by the Recipient. If the Recipient depletes its supply of Research Material or destroys the Research Material pursuant to this Paragraph 5 Recipient will so notify Provider in writing.**

5. Except as amended herein, all other terms and conditions of the MTA remain in full force and effect.

The Parties hereby accept and agree to the terms and conditions of this Second Amendment.

**SIGNATURES BEGIN ON NEXT PAGE**

IN WITNESS WHEREOF, the authorized Parties hereto have caused this Second Amendment to be duly executed and to be effective as of the Second Amendment Effective Date.

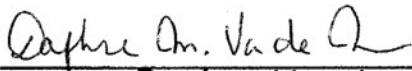
**National Institute of Allergy and Infectious Diseases, National Institutes of Health ("Provider"):**

Benjamin E. Hurley -S  
Digitally signed by Benjamin E. Hurley -S  
Date: 2018.07.16 09:34:43 -04'00'

Date: July 16, 2018

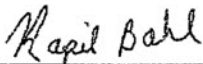
Benjamin Hurley  
TTPS, TTIPO, NIAID, NIH

**ModernaTX, Inc. ("Recipient"):**

  
Name **Daphne Van de Meerssche**  
Title **Counsel, Transactions**

Date: July 18, 2018

Read & Understood by Recipient Investigator

  
Kapil Bahl, Ph.D.  
Senior Scientist, ModernaTX, Inc.

Date: 7/18/18

IN WITNESS WHEREOF, the authorized Parties hereto have caused this Second Amendment to be duly executed and to be effective as of the Second Amendment Effective Date.

**National Institute of Allergy and Infectious Diseases, National Institutes of Health ("Provider"):**

Benjamin E. Hurley - Digitally signed by Benjamin E. Hurley-S  
Date: 2018.07.16 09:33:45 -04'00'  
S

Date: July 16, 2018

Benjamin Hurley  
TPPS, TTIPO, NIAID, NIH

**ModernaTX, Inc. ("Recipient"):**

*Daphne M. Van de Meer*

Date: 07/18/2018

Name

Title **Daphne Van de Meerssche  
Counsel, Transactions**

Read & Understood by Recipient Investigator

*Kapil Bahl*

Date: 7/18/18

Kapil Bahl, Ph.D.  
Senior Scientist, ModernaTX, Inc.

## RESEARCH COLLABORATION AGREEMENT

This Research Collaboration Agreement (“Agreement”) is between the National Institute of Allergy and Infectious Diseases (“NIAID”), which is a component of the National Institutes of Health (“NIH”), an agency of the U.S. Department of Health and Human Services, having offices located at 5601 Fishers Lane, Rockville, MD 20852, and ModernaTX, Inc. (“Moderna” or “Collaborator”), having a principal place of business at 200 Technology Square, Cambridge, MA 02139 and incorporated in the State of Delaware (collectively, the “Parties”). This Agreement is neither a funding agreement as defined in 35 U.S.C. § 201(b) nor a cooperative research and development agreement authorized under the Federal Technology Transfer Act of 1986, as amended, 15 U.S.C. §§ 3710a *et seq.*, and Executive Order 12591 of April 10, 1987. NIAID enters into this Agreement pursuant to the authority of the Public Health Services Act of 1944, as amended (42 U.S.C. § 241).

### BACKGROUND

1. NIAID and Collaborator want to collaborate on a research project; and
2. NIAID and Collaborator want to transfer between the laboratories of their investigators, during the term of this Agreement, proprietary research materials required to conduct the research project.

### TERMS AND CONDITIONS

#### Article 1 DEFINITIONS

- 1.1 “Affiliate” means any corporation or other business entity controlled by, controlling, or under common control with Collaborator at any time during the term of this Agreement. For this purpose, “control” means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or at least fifty percent (50%) interest in the income of the corporation or other business entity.
- 1.2 “Confidential Information” includes scientific, business, or financial information pertaining to the Research Project (defined below) that is disclosed by Provider (defined below). Confidential Information does not include information that: (i) is in the public domain other than as a result of a disclosure by Recipient (defined below) or any of Recipient’s representatives in violation of this Agreement; (ii) was in the possession of Recipient before disclosure by the Provider; (iii) is acquired by Recipient from a third party having no obligation of confidentiality to Provider; (iv) is hereafter independently developed by Recipient, without reference to Confidential Information received from Provider; or (v) Provider expressly authorizes Recipient to disclose.
- 1.3 “Invention” means any invention or discovery that is or may be patentable or protectable under applicable laws.
- 1.4 “Investigator” means the principal researcher designated by a Party to direct the Research Project.
- 1.5 “Material” means Original Material, Progeny, and any material created by Recipient that constitutes an unmodified functional subunit of or product expressed by Original Material including but not limited to subclones of unmodified cell lines, purified or fractionated subsets, proteins expressed by DNA/RNA, or monoclonal antibodies secreted by a hybridoma cell line.
- 1.6 “Original Material” means a material provided by one of the Parties to be used in the Research Project.
- 1.7 “Progeny” means unmodified descendent from Material, such as virus from virus, cell from cell, or organism from organism.



- 1.8 "Provider" means the Party that provides Original Material or discloses Confidential Information to the other Party under this Agreement. "Provider" includes, with respect to Collaborator, Affiliates of Collaborator.
- 1.9 "Recipient" means the Party that receives Original Material or Confidential Information from the other Party under this Agreement. "Recipient" includes, with respect to Collaborator, Affiliates of Collaborator.
- 1.10 "Research Project" means the collaborative research described in Appendix A.

## **Article 2 COLLABORATIVE RESEARCH**

- 2.1 NIAID and Collaborator agree to collaborate on the Research Project. The Investigator for NIAID will be Barney Graham, MD, PhD, and the Investigator for Collaborator will be Sunny Himansu.
- 2.2 Nothing in this Agreement will be construed to limit the freedom of either Party from engaging in similar research with other parties, providing the research does not create a conflict with the Parties' obligations under this Agreement, especially with regard to Article 3.
- 2.3 The Parties recognize that the Research Project describes the collaborative research to be conducted under this Agreement and that the goals set forth in Appendix A are good faith guidelines. If events occur that require substantial modification of the Research Project, the Parties may amend Appendix A according to Paragraph 6.9 of this Agreement.

## **Article 3 CONFIDENTIALITY; PUBLICATIONS**

### **3.1 Confidential Information**

- 3.1.1 Either Party may disclose or receive Confidential Information under this Agreement.
- 3.1.2 The Disclosing Party shall use reasonable efforts to (a) mark Confidential Information in any written document, memorandum, report, correspondence, drawing, or other tangible material as "Confidential Information" or "Confidential" and (b) reduce oral disclosures of Confidential Information, or disclosures through observation of Confidential Information, to a writing marked "Confidential Information" or "Confidential" within 30 days after disclosure to be considered Confidential Information. Notwithstanding the above, failure to mark information as "Confidential" will not disqualify that information from constituting "Confidential Information" under this Agreement if a reasonable person would consider such information to be confidential based on the nature of such information and the circumstances of disclosure.
- 3.1.3 Recipient will maintain Confidential Information in confidence for a period of five (5) years from the Effective Date and will protect Confidential Information with the same degree of care as Recipient uses to protect its own Confidential Information but in no event less than a reasonable standard of care.
- 3.1.4 Recipient may disclose Confidential Information to its and its Affiliates' employees, consultants, or contractors to whom it is necessary to disclose this information for the purpose of the Research Project; Recipient may make these disclosures only under terms at least as restrictive as those specified in this Agreement. Recipient agrees that disclosure of Confidential Information may not be made to any party not listed herein unless Provider grants prior written approval to Recipient.
- 3.1.5 Recipient may disclose Provider's Confidential Information if required to do so by law, regulation, or court order. If Recipient, or anyone to whom it discloses Confidential Information in accordance with Article 3, becomes legally required to disclose any

Confidential Information, Recipient will provide timely notice to Provider and, to the extent practicable, consult with Provider prior to any disclosure.

3.1.6 Either Party may disclose the existence of the Agreement to the public but any further information regarding the Research Project conducted under the Agreement will be limited to the following language: *"NIAID and Moderna will collaborate to evaluate immunogenicity of mRNA vaccines for Middle East Respiratory Syndrome coronavirus (MERS-CoV) and Nipah virus in animal models."* Proprietary Info

Proprietary Info

Proprietary Info

3.1.7 Proprietary Info

### 3.2 Publications; Press Releases

#### 3.2.1 Publications

3.2.1.1 In addition to the specific goals of the Research Project, the Parties view dissemination of research findings, both by publication and oral presentation, as an essential objective of the Research Project. Authorship will be decided according to commonly accepted conventions for scientific publications.

3.2.1.2 The Parties are encouraged to make publicly available the Results of the Research Project. Proprietary Info

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Proprietary Info

Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about the Results or any Invention made in the course of the Research Project, the other Party will have 30 days to review proposed manuscripts and 7 days to review proposed abstracts to ensure that Confidential Information and/or Inventions are protected. Either Party will have the right to remove any Confidential Information of that Party and its Affiliates from any such proposed publication or other public disclosure and will make a good faith effort to provide substitute information, if available, in the case that such information is necessary for the proposed publication to proceed; Proprietary Info

Proprietary Info

addition, either Party may request in writing that the proposed publication or other disclosure be delayed for up to 30 additional days as necessary to file a patent application.

#### 3.2.2 Press Releases

Press releases that reference or rely upon the research under this Agreement will be made available to the other Party for review and comment at least 7 days prior to publication.

**Article 4 INVENTIONS; DATA**

**4.1 Inventions**

- 4.1.1 The Parties acknowledge the possibility that Inventions may be made in the performance of the Research Project. Ownership of such Inventions will follow inventorship, which will be determined in accordance with applicable U.S. laws and regulations.
- 4.1.2 Inventions made in the performance of the Research Project will be owned by the Party employing the inventor or inventors. Inventions made in the performance of the Research Project that are invented jointly by employees of both Parties will be owned jointly. For clarity, references to "employee(s)" of a Party in this Section 4.1.2 shall include employees and agents of such Party and its Affiliates that are conducting or performing activities as a part of the Research Project.
- 4.1.3 Each Party will report to the other Party, in writing, all Inventions made in the performance of the Research Project no later than three (3) months from the time the invention is disclosed to a Party by its Investigator. The reports will be written in sufficient detail to determine inventorship and will be treated as Confidential Information in accordance with Article 3. The Parties will confer with each other regarding a patent filing strategy for jointly made Inventions. If either Party files a patent application on a jointly made Invention, then the filing Party will include a statement in the patent application that clearly identifies the Parties and states that the Invention was made jointly under this Agreement.

4.1.4 Proprietary Info

**4.2 Data**

Upon the request of the other Party, each Party will disclose to the other Party a summary of all data, information and results generated from the use of the Material(s) in the performance of the Research Project under this Agreement ("Results"). The Parties may use the Results for their own internal purposes, but shall otherwise treat the Results as "Confidential Information" of the other Party until published in accordance with Article 3.2; provided that the Parties shall have the right to disclose the Results prior to publication in connection with any regulatory or patent filing. Further, Collaborator shall have the right to disclose the Results prior to publication to (a) Collaborator's actual or potential investors who are not pharmaceutical, biotech, or other companies primarily engaged in the business of discovering, developing, manufacturing or the marketing of pharmaceutical product, (b) Collaborator's bona fide third party collaborators as of the Effective Date, Proprietary Info and (c) with the prior written consent of NIAID, bona fide collaborators of Collaborator arising after the Effective Date, provided that in each case ((a)-(c)) such actual or potential investors and third party collaborators are bound by written agreement to treat the Results as confidential and such written agreements contain confidentiality obligations at least as restrictive as those herein.

**Article 5 THE TRANSFER AND USE OF MATERIAL**

**5.1 Mechanics of Transfer**

Either Party may provide or receive Original Material under this Agreement. Provider will send Original Material to Recipient with a cover letter as described in Appendix B. The letter will refer

to this Agreement and identify Original Material. If either Party transfers to the other Party a material not listed in Appendix A, the Parties will amend this Agreement to include the additional material.

## 5.2 Conditions of Use

5.2.1 RECIPIENT WILL NOT USE MATERIAL IN RESEARCH INVOLVING HUMAN SUBJECTS.

5.2.2 Recipient's Investigator will use Material solely in connection with the Research Project in the Investigator's laboratory. If Recipient wants to use Material for commercial purposes, Recipient agrees to first obtain the appropriate commercial use or commercialization license from Provider.

5.2.3 Recipient agrees that Recipient's Investigator will retain control over Material and further agrees that Recipient's Investigator will not transfer Material to people not under the Investigator's direct supervision without advance written approval of Provider.

5.2.4 Proprietary Info



5.2.5 Recipient will use Material in compliance with all applicable laws, regulations and policies.

5.2.6 Nothing in this Agreement shall restrict Provider from using or distributing its Original Materials.

5.2.7 Upon termination of this Agreement, Recipient agrees that Recipient's Investigator will return any and all remaining Original Material unless Provider gives Recipient's Investigator directions for disposing of Original Material by another means.

5.2.8 Nothing in this Agreement will be construed as conferring on Recipient any implied license to Material, or option to license Material, any technology, or any patent or patent application owned by Provider and will not create any obligation, by implication or otherwise, of either Party to enter into any further agreement with the other Party.

## Article 6 TERMINATION AND GOVERNANCE

### 6.1 Effective Date

This Agreement will be effective on the date of the last authorized signature below.

### 6.2 Term and Termination

6.2.1. The Parties agree that this Agreement will be effective for three (3) years from the date of the last authorized signature below and may be extended as mutually agreed by the Parties in a written amendment to this Agreement.

6.2.2 This Agreement will terminate immediately upon the mutual agreement of the Parties in writing.

6.2.3 This Agreement will terminate in 30 days after either Party receives written notice of the other Party's desire to terminate this Agreement.

### 6.3 Representations, Warranties, and Liability

6.3.1 Material is understood to be experimental in nature and may have hazardous properties. ORIGINAL MATERIAL IS BEING SUPPLIED TO RECIPIENT WITH NO

WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of Material will not infringe any patent or other proprietary rights of third parties.

6.3.2 No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement. Each Party will be liable for any loss, claim, damage, or liability that the Party incurs as a result of its activities under this Agreement, except that NIAID, as an agency of the U.S. Government, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. §§ 2671 *et seq.*

#### 6.4 Assignment

Neither this Agreement nor any rights or obligations of either Party hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party. Proprietary

Proprietary Info

Proprietary Info

This Agreement will be binding upon the Parties and their respective successors and permitted assigns.

#### 6.5 Non-endorsement

By entering into this Agreement, NIAID does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to this Agreement, by Collaborator, its successors, permitted assigns, or licensees. Collaborator will not in any way state or imply that this Agreement is an endorsement of any such product or service by the U.S. Government or any of its organizational units or employees.

#### 6.6 Survivability

Articles 3, 4, 5.2, 6.3, 6.5, 6.6 and 6.8 will survive expiration or earlier termination of this Agreement.

#### 6.7 Severability

The illegality or invalidity of any provisions of this Agreement will not impair, affect, or invalidate the other provisions of this Agreement.

#### 6.8 Governing Law

The construction, validity, performance, and effect of this Agreement will be governed by federal law as applied by the federal courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement.

#### 6.9 Entire Agreement

This Agreement, together with all appendices, constitutes the entire agreement between the Parties and supersedes any prior or contemporaneous oral or written agreements or communications between them with respect to the subject matter hereof. This Agreement may be amended only by written instrument signed by authorized representatives of NIAID and Collaborator.

#### 6.10 Notices

All notices pertaining to or required by this Agreement shall be in writing, shall be signed by an authorized representative and shall be delivered to the addresses indicated on the signature page for each Party.

**SIGNATURES BEGIN ON THE NEXT PAGE**

FOR NIAID:

Vincent J. Felliccia

Vincent Felliccia, PhD, JD  
Branch Chief, TTIPO, NIAID

5/14/2019  
Date

Mailing Address for Notices:

ATTN: COLLABORATION AGREEMENT  
TECHNOLOGY TRANSFER AND INTELLECTUAL PROPERTY OFFICE, NIAID  
Suite 6D, MSC 9804, 5601 Fishers Lane  
Rockville, MD 20852  
Tel: 301-496-2644 / Fax: 240-627-3117

Acknowledgment by NIAID's Investigators:

[Signature]

Barney Graham, MD, PhD  
Deputy Director, VRC, NIAID

19 June 2019  
Date

FOR ModernaTX, Inc.:

MICHAEL WATSON, SVP Vaccines, Partnerships + Access

Printed name  
Title

05/13/2019  
Date

Mailing Address for Notices:

ModernaTX, Inc.  
200 Technology Square  
Cambridge, MA 02139

Tel: +1 617 674 5695

Fax: +1 617 583 1998

Acknowledgment by Moderna's Investigator:

[Signature]

Sunny Himansu  
Sr. Manager, Infectious Disease Research

05/13/2019  
Date

## APPENDIX A

### Research Project

#### Evaluation of an mRNA vaccine for Zika virus

- I. Abstract of the Research Project – for Public Release**  
EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION,  
RELEASE THIS ABSTRACT TO THE PUBLIC.

NIAID and Moderna will collaborate to evaluate immunogenicity of mRNA vaccines for Middle East Respiratory Syndrome coronavirus (MERS-CoV) and Nipah virus in animal models.

**II. Goal(s) of Project**

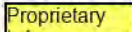
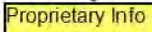
*The goals of this project are to:*

-  Proprietary Info
- 

**III. Background**

MERS-CoV and Nipah virus are potential epidemic threats and have been recognized on the World Health Organization's list of top emerging diseases likely to cause major epidemics and Coalition for Epidemic Preparedness Innovations priority pathogens list. No vaccines to prevent MERS-CoV or Nipah virus infection are currently available. Thus, there is a need to rapidly develop vaccine candidates that could be used to prevent MERS-CoV and Nipah virus infection in case of an outbreak. Nucleic acid-based vaccine platforms allow for rapid generation of vaccine candidates using reverse genetics. In this collaborative project, we will evaluate immunogenicity of mRNA vaccines for MERS-CoV and Nipah virus in animal models.

The Vaccine Research Center, NIAID ("VRC/NIAID") has extensive experience with the development of vaccines against infectious diseases and structure-based design of vaccine candidates. In particular, VRC/NIAID has developed stabilized prefusion MERS-CoV spike protein, which is more immunogenic than wild-type or subunit proteins. This stabilized prefusion protein is currently being evaluated in preclinical studies. Based on the VRC's prior experience stabilizing the fusion (F) protein in its prefusion conformation with the related respiratory syncytial virus and parainfluenza virus 3 (PIV3), the VRC has designed stabilized Nipah F proteins which are currently being evaluated in preclinical studies.

Moderna has developed a proprietary mRNA vaccine platform, and has used this for development of vaccines that are currently being evaluated in Phase I clinical trials. In addition, Moderna is evaluating a  MERS  mRNA vaccine in animal models. Moderna has also developed a HMPV/PIV3 vaccine that is in clinical development which targets two viruses including PIV3 which is in the same paramyxoviridae family as Nipah virus.

The purpose of these studies is to evaluate immunogenicity of mRNA vaccines for MERS-CoV and Nipah virus in animal models.



**IV. Original Materials Contributed by the Parties**

- i. VRC, NIAID Original Material:**  
Including but not limited to:

Proprietary Info

- ii. Collaborator Original Material:**

Proprietary Info

**V. Respective Contributions of the Parties**

**VRC, NIAID will:**

Proprietary Info

**Collaborator will:**

Proprietary Info

**Both Parties will:**

- Share data and materials
- Discuss results and plan next steps

**VI. Experimental Plan**

- 1.
- 2.
- 3.
- 4.

Proprietary Info

Both parties will share and discuss the results.

## APPENDIX B

### Sample Material Transfer Cover Letter

*A sample letter follows.*

Date

Provider Organization Name  
Provider Organization Address  
Tel:  
Fax:

Recipient PI  
Recipient Organization  
Recipient Organization Address

**RE: TRANSFER OF MATERIAL(S) UNDER COLLABORATION AGREEMENT BETWEEN NIAID AND  
[NAME OF COLLABORATOR] DATED [MONTH/YEAR]**

**DEAR DR. [NAME OF NIAID PI OR COLLABORATOR PI]:**

The [National Institute of Allergy and Infectious Diseases (NIAID) or Collaborator] is pleased to provide you with the following material(s): [Describe material(s)]. The material(s) developed by [insert name], are being shipped to you by [NIAID/ Collaborator].

The material(s) may only be used for research conducted between NIAID and [Collaborator] under the Collaboration Agreement referenced above. In addition, you understand that any remaining material(s) will be returned to [NIAID/ Collaborator] or disposed of according to the written instructions of [NIAID/ Collaborator] when the Collaboration Agreement expires, unless [NIAID/ Collaborator] obtains permission from [NIAID/ Collaborator] to continue using the materials.

Please acknowledge receipt of the material(s) by signing below. At your earliest convenience, please fax a copy of this letter to your technology transfer office at [NIAID/ Collaborator].

Sincerely,

NIAID/ Collaborator [Provider]  
Title  
cc:

Acknowledged by NIAID/ Collaborator PI [Recipient]

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name and Title

## Research Collaboration Agreement 2017-1179

### Amendment Number One (1)

The purpose of this Amendment is to change certain terms of the Research Collaboration Agreement (RCA) executed May 14, 2019 between the National Institute of Allergy and Infectious Diseases (NIAID) and ModernaTX, Inc. (“Moderna”). These changes are reflected below, and except for these changes, all other provisions of the original RCA shall remain in full force and effect. This Agreement may be executed in one or more counterparts, each of which together shall be deemed original but all of which together shall constitute one and the same document. A facsimile or Portable Document Format (PDF) of the original signature of the representative of a party shall have the same validity as an original signature for the purpose of this Agreement. For purposes of identification, the NIAID reference number of the original RCA is 2017-1179.

The above-referenced RCA is amended as follows:

1. Upon final signature, Appendix A will read as follows (all additions are shown in underline and all deletions are shown in ~~strikeout~~):

#### APPENDIX A

#### Research Project

#### I. Evaluation of an mRNA vaccine for Nipah virus and Middle East Respiratory Syndrome coronavirus

##### I. Abstract of the Research Project – for Public Release

EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION,

RELEASE THIS ABSTRACT TO THE PUBLIC.

NIAID and Moderna will collaborate to evaluate immunogenicity of mRNA vaccines for Middle East Respiratory Syndrome coronavirus (MERS-CoV) and Nipah virus in animal models.

#### II. Goal(s) of Project

*The goals of this project are to:*

-  Proprietary Info
- 

#### III. Background

MERS-CoV and Nipah virus are potential epidemic threats and have been recognized on the World Health Organization’s list of top emerging diseases likely to cause major epidemics and Coalition for Epidemic Preparedness Innovations priority pathogens list. No vaccines to prevent MERS-CoV or Nipah virus infection are currently available. Thus, there is a need to rapidly develop vaccine candidates that could be used to prevent MERS-CoV and Nipah virus infection in case of an outbreak. Nucleic acid-based vaccine platforms allow for rapid generation of vaccine candidates using reverse

genetics. In this collaborative project, we will evaluate immunogenicity of mRNA vaccines for MERS-CoV and Nipah virus in animal models.

The Vaccine Research Center, NIAID (“VRC/NIAID”) has extensive experience with the development of vaccines against infectious diseases and structure-based design of vaccine candidates. In particular, VRC/NIAID has developed stabilized prefusion MERS-CoV spike protein, which is more immunogenic than wild-type or subunit proteins. This stabilized prefusion protein is currently being evaluated in preclinical studies. Based on the VRC’s prior experience stabilizing the fusion (F) protein in its prefusion conformation with the related respiratory syncytial virus and parainfluenza virus 3 (PIV3), the VRC has designed stabilized Nipah F proteins which are currently being evaluated in preclinical studies.

Moderna has developed a proprietary mRNA vaccine platform, and has used this for development of vaccines that are currently being evaluated in Phase I clinical trials. In addition, Moderna is evaluating a Proprietary Info MERS Proprietary protein mRNA vaccine in animal models. Moderna has also developed a HMPV/PIV3 vaccine that is in clinical development which targets two viruses including PIV3 which is in the same paramyxoviridae family as Nipah virus.

The purpose of these studies is to evaluate immunogenicity of mRNA vaccines for MERS-CoV and Nipah virus in animal models.

**IV. Original Materials Contributed by the Parties**

- i. **VRC, NIAID Original Material:**  
Including but not limited to:

Proprietary Info

- ii. **Collaborator Original Material:**

Proprietary Info

**V. Respective Contributions of the Parties**

**VRC, NIAID will:**

Proprietary Info

**Collaborator will:**

Proprietary Info

- Proprietary Info

**Both Parties will:**

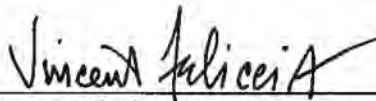
- Share data and materials
- Discuss results and plan next steps

**VI. Experimental Plan**

1. Proprietary Info
- 2.
- 3.


4. Both parties will share and discuss the results.

**ACCEPTED AND AGREED TO:  
FOR NIAID:**

  
\_\_\_\_\_  
Vincent Fellicia, PhD, JD  
Branch Chief, TTIPO, NIAID

1/13/2020  
\_\_\_\_\_  
Date

**FOR MODERNA:**

  
\_\_\_\_\_  
Andrea Carfi, PhD  
Head, Infectious Disease Research, Moderna

12/16/14  
\_\_\_\_\_  
Date

## MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement ("MTA") has been adopted for use by the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute at the National Institutes of Health, which is part of the Department of Health and Human Services, an agency of the United States Government ("Provider") in transfers of research material to for-profit institutions for internal research.

Recipient: **ModernaTX, Inc.**, having offices at 500 Technology Square Cambridge, MA 02139, created and operating under the laws of Delaware.

1. Provider agrees to transfer to Recipient's Investigator the following material(s), including known functional components or subunits and unmodified descendants thereof ("Research Material"):

Name/Description	Reference
<u>Cell line #1: RajiDCSIGN</u>	PMID: 16415006 and PMID: 18005691
<u>Cell line #2: RajiDCSIGNR</u>	PMID: 16415006 and PMID: 18005691

2. **THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS.** The Research Material will only be used for commercial research purposes by Recipient's Investigator in his/her laboratory, for the research project described below, under suitable containment conditions. **The Research Material will not be used in any product offered for sale or processes for the manufacture thereof, including quality control procedures, or in commercial services for which a commercialization license from the National Institutes of Health ("NIH") is required. The Research Material and methods of using the Research Material are the subject of U.S. and foreign patent applications. Please contact the TTIPO, NIAID, if information is desired concerning the present status of this invention or how to license the Research Material and/or patents covering the Research Material.**

Recipient agrees to comply with all laws, rules and regulations applicable to the Research Project and the handling of the Research Material.

- a. Is the Research Material of human origin?
- Yes       No
- b. If Yes in 2a, was Research Material collected according to 45 C.F.R. Part 46, "Protection of Human Subjects"?
- Yes      Please provide Assurance Number: \_\_\_\_\_
- No
3. This Research Material will be used by Recipient's Investigator solely in connection with the following research project ("Research Project") described with specificity as follows:

The Recipient will use the Research Material to perform neutralizing titer assays **Proprietary Info** **Proprieta** as an immunogenicity readout for several *in vivo* studies the Recipient will run in support of its vaccine programs **Proprietary Info**

4. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's contribution of this Research Material unless requested otherwise. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of Provider's written information about this Research Material that is stamped "CONFIDENTIAL," except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from Provider to Recipient shall be identified as being CONFIDENTIAL by notice delivered to Recipient within ten (10) days after the date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if Provider has given CONFIDENTIAL information to Recipient such public disclosure may be made only after Provider has had thirty (30) days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information, except when a shortened time period under court order or the Freedom of Information Act pertains.
5. This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient therefore agrees that Recipient's Investigator will retain control over this Research Material and further agrees that Recipient's Investigator will not transfer the Research Material to other people not under her or his supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. **When the Research Project is completed, or this MTA is terminated, or on 18 June 2018, whichever occurs first, the Research Material will be returned to the Provider or disposed of as directed by Provider. If the Recipient depletes its supply of Research Material or destroys the Research Material pursuant to this Paragraph 4 Recipient will so notify Provider in writing.**
6. This Research Material is provided as a service to the research community. **IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.
7. Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. Recipient agrees not to claim, infer, or imply governmental endorsement of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s). Each Party shall be responsible for its own negligence under this MTA. Unless prohibited by law from doing so, recipient agrees to hold the United States Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of any third party claim or suit in connection with the Recipient's use for any purpose of the Research Material, except to the extent that any such liability, demand, damage, expense or loss is attributable to Provider's negligence.
8. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.
9. This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.
10. In the event that Recipient wishes to use the Research Material for commercial purposes other than the commercial research described in Paragraph 3 above, Recipient agrees to first obtain from NIH the appropriate commercial use or commercialization license.
11. Either Provider or Recipient may unilaterally terminate this MTA at any time by giving written notice to the other Party at least thirty (30) days prior to the desired termination date.
12. The provisions of Paragraphs 4, 5, 7, 9, 10 and 12 of this MTA will survive expiration or termination.

13. This MTA may be executed in counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument. A facsimile, scanned electronic signature or certified electronic signature shall be as effective as an original signature.
14. The Research Material will be used for the Research Project described in Article 3 only. The Research Material will not be used in research projects:
- (a) involving collaboration with another for-profit organization;
  - (b) sponsored or funded by another for-profit organization;
  - (c) in which Recipient or Recipient's Investigator is obligated to assign inventions containing the Research Material or offer an exclusive license to inventions containing the Research Material to an organization other than Recipient or a contractor of Recipient that manages Recipient's inventions on behalf of Recipient; or
  - (d) in which Recipient or Recipient's Investigator is obligated to receive permission from an organization other than Recipient before publicly disclosing results of research involving the Research Material.

**NOTE:** If Recipient wishes to use the Research Material in a research project that is forbidden above, Recipient should contact the Technology Transfer and Intellectual Property Office (TTIPO), National Institute of Allergy and Infectious Diseases (NIAID), to discuss whether permission to use the Research Material in such project can be obtained.


SIGNATURES BEGIN ON NEXT PAGE



# MATERIAL TRANSFER AGREEMENT

## SIGNATURE PAGE

### FOR RECIPIENT:

Recipient's Investigator  
  
Signature


Scott Butler, PhD  
Director of Virology & Project Leader

Date: 10/25/2017

Mailing Address for Materials:

Moderna  
500 Technology Square  
Cambridge, MA 02139  
Attn: Brooke Bollman

Tel: (781) 434-8246  
Email: Scott.butler@valeratx.com

Duly Authorized  
  
Signature

Giuseppe Ciaramella  
Printed Name and Title

Date: 10/25/2017

Mailing Address for Notices:

500 Technology Square  
Cambridge, MA 02139

Tel: Fax:

### FOR PROVIDER:

Provider's Investigator

Theodore Pierson, Ph.D.  
Chief, Viral Pathogenesis Section  
Laboratory of Viral Diseases  
NIAID

Date: \_\_\_\_\_

Mailing Address:

Bldg 33 RM 2E19A2  
33 North Drive  
Bethesda, MD 20892

Tel: 301/451-7977 Fax: 301/451-7978

Duly Authorized

Christopher M. Kornak -S  
Digitally signed by Christopher M. Kornak -S  
Date: 2017.10.25 10:08:03 -04'00'

Chris Kornak, J.D., M.S.  
Lead TTPS, Technology Transfer and Intellectual  
Property Office  
NIAID

Date: 10-25-2017

Mailing Address for Notices:

TECHNOLOGY TRANSFER AND INTELLECTUAL  
PROPERTY OFFICE  
NIAID, NIH  
Suite 6D, MSC 9804  
5601 Fishers Lane  
Rockville, MD 20852  
301-496-2644 (Office)

Tel: 301/496-2644 Fax: 301/402-7123

**AMENDMENT NUMBER ONE TO  
MATERIAL TRANSFER AGREEMENT**

This Amendment Number One (the "First Amendment") to the Material Transfer Agreement ("MTA")(NIAID Reference Number 2017-1210), having an effective date of October 25, 2017 is entered into as of the date of last authorized signature hereto (the "First Amendment Effective Date") and made by and between National Institute of Allergy and Infectious Diseases, National Institutes of Health, with its principal place of business at 5601 Fishers Lane, Suite 6D, MSC 9804, Rockville, MD 20852 ("Provider") and ModernaTX, Inc., having offices at 200 Technology Square Cambridge, MA 02139, created and operating under the laws of Delaware ("Recipient"). Each of Provider and Recipient may be referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, Provider and Recipient desire that the MTA be amended a first time as set forth below in order to modify the scope of the MTA Research Project Proprietary Info

Proprietary Info

Proprietary Info; and

WHEREAS, the Parties have been operating under the MTA and desire to extend the term of MTA-FP 2017-1210 by one (1) month to July 18, 2018 while Company and NIAID conclude negotiations/finalization of License Agreement A-261-2018 and corresponding MTA-FP 2018-0664; and

WHEREAS, the Parties desire to amend the MTA as set forth in this First Amendment.

NOW, THEREFORE, the Parties hereby agree as follows:

1. Unless otherwise defined herein, capitalized terms used in this First Amendment have the meanings assigned thereto in the MTA.
2. This First Amendment may be signed by each Party separately on different signature pages, and each document when fully signed by a Party and delivered shall constitute an original instrument, and all such multiple signed documents shall constitute one and the same instrument. This First Amendment shall be effective as of the date of the final authorized signature hereto, the First Amendment Effective Date. Execution by the Parties shall be by original signature, electronic signature, or copy of signature received via portable document format (PDF) and an electronic signature or a PDF signature shall be deemed to be and shall be as effective as an original signature.
3. The description of the Research Project in paragraph 3 of the MTA is hereby deleted and replaced by the following:

**The Recipient's use of the Research Material will be confined solely to the scope of "Zika virus vaccine development" as limited to and defined by the HHS0100201600029C BARDA-funded Zika virus vaccine development award.**

4. Paragraph 5 of the MTA is hereby deleted and replaced with the following:

This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient therefore agrees that Recipient's Investigator will retain control over this Research Material and further agrees that Recipient's Investigator will not transfer the Research Material to other people not under her or his supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. **When the Research Project is completed, or this MTA is terminated, or on 18 July 2018, whichever occurs first, the Research Material will be destroyed by the Recipient. If the Recipient depletes its supply of Research Material or destroys the Research Material pursuant to this Paragraph 5 Recipient will so notify Provider in writing.**

5. Except as amended herein, all other terms and conditions of the MTA remain in full force and effect.

The Parties hereby accept and agree to the terms and conditions of this First Amendment.

**SIGNATURES BEGIN ON NEXT PAGE**

IN WITNESS WHEREOF, the authorized Parties hereto have caused this First Amendment to be duly executed and to be effective as of the First Amendment Effective Date.

**National Institute of Allergy and Infectious Diseases, National Institutes of Health ("Provider"):**

Benjamin E. Hurley -S  
Digitally signed by Benjamin E. Hurley -S  
Date: 2018.06.15 10:26:11 -04'00'

Benjamin Hurley  
TTPS, TTIPO, NIAID, NIH

Date: 15 June 2018

**ModernaTX, Inc. ("Recipient"):**

Daphne M. Van de Meerssche  
Name Daphne M. Van de Meerssche  
Title Counsel

Date: June 18, 2018

Read & Understood by Recipient Investigator

Kapil Bahl  
Kapil Bahl, Ph.D.  
Senior Scientist, ModernaTX, Inc.

Date: June 18, 2018

**AMENDMENT NUMBER TWO TO  
MATERIAL TRANSFER AGREEMENT**

This Amendment Number Two (the "Second Amendment") to the Material Transfer Agreement ("MTA")(NIAID Reference Number 2017-1210), having an effective date of October 25, 2017 is entered into as of the date of last authorized signature hereto (the "Second Amendment Effective Date") and made by and between National Institute of Allergy and Infectious Diseases, National Institutes of Health, with its principal place of business at 5601 Fishers Lane, Suite 6D, MSC 9804, Rockville, MD 20852 ("Provider") and ModernaTX, Inc., having offices at 200 Technology Square Cambridge, MA 02139, created and operating under the laws of Delaware ("Recipient"). Each of Provider and Recipient may be referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, Provider and Recipient desire that the MTA be amended a second time as set forth below in order to modify the scope of the MTA Research Project Proprietary Info

Proprietary Info

Proprietary Info

and

WHEREAS, the Parties have been operating under the MTA and desire to extend the term of MTA-FP 2017-1210 by two (2) months to August 18, 2018 while Company and NIAID conclude negotiations/finalization of License Agreement A-261-2018 and corresponding MTA-FP 2018-0664; and

WHEREAS, the Parties desire to amend the MTA as set forth in this Second Amendment.

NOW, THEREFORE, the Parties hereby agree as follows:

1. Unless otherwise defined herein, capitalized terms used in this Second Amendment have the meanings assigned thereto in the MTA.
2. This Second Amendment may be signed by each Party separately on different signature pages, and each document when fully signed by a Party and delivered shall constitute an original instrument, and all such multiple signed documents shall constitute one and the same instrument. This Second Amendment shall be effective as of the date of the final authorized signature hereto, the Second Amendment Effective Date. Execution by the Parties shall be by original signature, electronic signature, or copy of signature received via portable document format (PDF) and an electronic signature or a PDF signature shall be deemed to be and shall be as effective as an original signature.
3. The description of the Research Project in paragraph 3 of the MTA is hereby deleted and replaced by the following:

**The Recipient's use of the Research Material will be confined solely to the scope of "Zika virus vaccine development" as limited to and defined by the HHS0100201600029C BARDA-funded Zika virus vaccine development award.**

4. Paragraph 5 of the MTA is hereby deleted and replaced with the following:

This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient therefore agrees that Recipient's Investigator will retain control over this Research Material and further agrees that Recipient's Investigator will not transfer the Research Material to other people not under her or his supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. **When the Research Project is completed, or this MTA is terminated, or on 18 August 2018, whichever occurs first, the Research Material will be destroyed by the Recipient. If the Recipient depletes its supply of Research Material or destroys the Research Material pursuant to this Paragraph 5 Recipient will so notify Provider in writing.**

5. Except as amended herein, all other terms and conditions of the MTA remain in full force and effect.

The Parties hereby accept and agree to the terms and conditions of this Second Amendment.

**SIGNATURES BEGIN ON NEXT PAGE**

IN WITNESS WHEREOF, the authorized Parties hereto have caused this Second Amendment to be duly executed and to be effective as of the Second Amendment Effective Date.

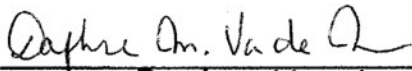
**National Institute of Allergy and Infectious Diseases, National Institutes of Health ("Provider"):**

Benjamin E. Hurley -S  
Digitally signed by Benjamin E. Hurley -S  
Date: 2018.07.16 09:34:43 -04'00'

Date: July 16, 2018

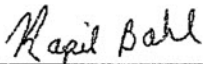
Benjamin Hurley  
TTPS, TTIPO, NIAID, NIH

**ModernaTX, Inc. ("Recipient"):**

  
Name **Daphne Van de Meerssche**  
Title **Counsel, Transactions**

Date: July 18, 2018

Read & Understood by Recipient Investigator

  
Kapil Bahl, Ph.D.  
Senior Scientist, ModernaTX, Inc.

Date: 7/18/18

IN WITNESS WHEREOF, the authorized Parties hereto have caused this Second Amendment to be duly executed and to be effective as of the Second Amendment Effective Date.

**National Institute of Allergy and Infectious Diseases, National Institutes of Health ("Provider"):**

Benjamin E. Hurley - Digitally signed by Benjamin E. Hurley-S  
Date: 2018.07.16 09:33:45 -04'00'  
S

Date: July 16, 2018

Benjamin Hurley  
TPPS, TTIPO, NIAID, NIH

**ModernaTX, Inc. ("Recipient"):**

Daphne M. Van de Meer

Date: 07/18/2018

Name

Title **Daphne Van de Meerssche  
Counsel, Transactions**

Read & Understood by Recipient Investigator

Kapil Bahl

Date: 7/18/18

Kapil Bahl, Ph.D.  
Senior Scientist, ModernaTX, Inc.



## Confidential Disclosure Agreement

In order to protect confidential information relating to research, development, business plans, and other technology, which may be disclosed between them, the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services, as represented by the Division of Microbiology and Infectious Diseases (“DMID”), and Moderna TX, Inc. and the following Affiliates of Moderna TX, Inc. (“Affiliate” means any corporation or other business entity controlled by, controlling, or under common control with Moderna TX, Inc. at any time during the term of this Agreement. For this purpose, “control” means direct or indirect beneficial ownership of more than fifty percent (50%) of the voting stock or more than fifty percent (50%) interest in the income of the corporation or other business entity): **Proprietary Info** collectively, the “Collaborator”) identified below (collectively the “Parties” and individually a “Party”), intending to be legally bound as of the date of the last authorized signature hereto (“Effective Date”), agree that:

1. A Party (“Disclosing Party”) may disclose information to the other (“Receiving Party”) for the purpose of assessing their interest in a research collaboration (the “Purpose”). The Disclosing Party is : **Collaborator**

2. The Parties’ representatives for disclosing or receiving information (if known):

**For DMID:** Carolyn Deal, Thomas Hiltke

**For Collaborator:** Nadia Cohen, and other employees of the Collaborator as needed to fulfill the Purpose

3. The information disclosed under this Agreement (“Confidential Information”) is described as:

Collaborator may disclose results of **Proprietary Info** studies of Collaborator’s candidate vaccines **Proprietary Info** non-public technical, business and financial information, including third party information for which Collaborator has an obligation to maintain as confidential, relating to the research, design, manufacture, development, and commercialization of messenger RNA (mRNA) and the use of mRNA for the treatment and prevention of disease.

4. The Receiving Party shall use Confidential Information of the Disclosing Party only for the Purpose, and for no other purpose. The Receiving Party will not disclose the Confidential Information of the Disclosing Party to any person except its employees, consultants, and contractors, to whom it is necessary to disclose the Confidential Information for the Purpose described above, and any such disclosures will be under terms at least as restrictive as those specified herein. Any of the persons mentioned above who are given access to the Confidential Information will be informed of this Agreement. The Receiving Party will protect the Confidential Information by using the same degree of care, but no less than a reasonable degree of care, as the Receiving Party uses to protect its own confidential information.

5. The Receiving Party’s duties under this Agreement will apply only to Confidential Information in any written document, memorandum, report, correspondence, drawing, or other tangible material, or computer software or program, developed or prepared by the Disclosing Party or any of its representatives that has been clearly marked “Confidential” by the Disclosing Party. Oral disclosures must be reduced to writing **Proprietary Info** and marked “Confidential” by the Disclosing Party within thirty (30) days after disclosure to be considered Confidential Information.

6. Notwithstanding any other provision of this Agreement, Confidential Information will not include any item of information, data, patent or idea that: (a) is within the public domain prior to the time of the disclosure by the Disclosing Party to the Receiving Party or thereafter becomes within the public domain other than as a result of disclosure by the Receiving Party or any of its representatives in violation of this Agreement; (b) was, on or before the date of disclosure in the possession of the Receiving Party; (c) is acquired by the Receiving Party from a third party not under an obligation of confidentiality; (d) is hereafter independently developed by the Receiving Party, without use of or reference to the Confidential Information received from the Disclosing Party; or (e) the Disclosing Party expressly authorizes in writing the Receiving Party to disclose.

7. At the request of the Disclosing Party, the Receiving Party agrees to return or destroy all Confidential Information received from the Disclosing Party except that the Receiving Party may retain in its confidential files one (1) copy of written Confidential Information for record purposes only.

8. If the Receiving Party, or anyone to whom it discloses the Confidential Information in accordance with Paragraph 4, becomes legally required to disclose any of the Confidential Information, the Receiving Party will, to the extent practicable, provide the Disclosing Party with timely notice and, to the extent practicable, consult with the Disclosing Party prior to any disclosure.

9. It is acknowledged that nothing herein will deem to constitute, by implication or otherwise, the grant to either Party by the other of any license or other rights under any patent, patent application or other intellectual property right or interest.

10. It is acknowledged and agreed by both Parties that each represents to the other Party that each Official signing this Agreement has authority to so do.

11. The illegality or invalidity of any provision of this Agreement will not impair, affect or invalidate the other provisions of this Agreement.

12. This Agreement is to be made under and will be construed in accordance with Federal laws as applied by the Federal Courts in the District of Columbia, and constitutes the entire understanding between the Parties with respect to the subject matter hereof and merges any and all prior agreements, understandings and representations with respect to the subject matter hereof. The Agreement may not be superseded, amended or modified except by written agreement between the Parties.

13. This Agreement will control Confidential Information disclosed only between the Effective Date and one (1) year thereafter and the remaining terms and conditions of this Agreement will expire four (4) years from the Effective Date. Either party may terminate this Agreement upon thirty (30) days written notice to the other Party.

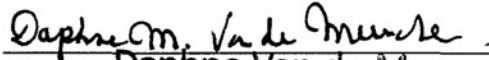
14. This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument. A facsimile, scanned electronic signature shall be as effective as an original signature.

**SIGNATURES BEGIN ON THE NEXT PAGE**

*ModernaTX, Inc.*

**National Institute of Allergy and Infectious  
Diseases  
Division of Microbiology and Infectious  
Diseases  
5601 Fishers Lane  
Room 7G51  
Bethesda MD 20892  
MSC 9826**

Authorized Signature:

  
Name: Daphne Van de Meerssche  
Title: Counsel, Transactions  
Date: December 8, 2017

Authorized Signature:

Emily J. Digitally signed by  
Emily J. Erbelding -S  
Date: 2017.12.08  
07:47:12 -05'00'  
Erbelding -S

Emily Erbelding, MD, MPH  
Director, Division of Microbiology and  
Infectious Diseases  
National Institute of Allergy and Infectious  
Diseases

Date: \_\_\_\_\_

Mailing Address for Notices:

5601 Fishers Lane  
Room 7F29  
Bethesda, MD 20892  
MSC 9826  
Ph. 240-292-0927

Acknowledged by DMID Representative(s) Disclosing/Receiving Confidential/Proprietary Information:

**(Branch/Office), DMID**

\_\_\_\_\_  
[name]

\_\_\_\_\_  
Date

\_\_\_\_\_  
*Thomas Little Stjibet*

\_\_\_\_\_  
Date *12/1/17*

\_\_\_\_\_  
*(Accession Done (Date))*

\_\_\_\_\_  
Date *12/1/17*

\_\_\_\_\_  
Date

**OCRA, DMID**

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Date

**ORA, DMID**

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Date

**OD, DMID**

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Date

**(Other)**

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Date

## MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement ("MTA") has been adopted for use by the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute at the National Institutes of Health, which is part of the Department of Health and Human Services, an agency of the United States Government ("Provider") in transfers of research material to for-profit institutions for internal research.

Recipient: **ModernaTX, Inc.**, having offices at 500 Technology Square Cambridge, MA 02139, created and operating under the laws of Delaware

1. Provider has previously transferred to Recipient's Investigator the following material(s), including known functional components or subunits and modified or unmodified descendants thereof ("Research Material"):

Name/Description	Reference
<i>Cell line #1:</i> RajiDCSIGN	PMID: 16415006 and PMID: 18005691
<i>Cell line #2:</i> RajiDCSIGNR	PMID: 16415006 and PMID: 18005691
pFurin; a DNA expression construct expressing human furin protease	Davis et al., J Virol. 2006 Feb; 80(3):1290-301. (PMID: 16415006)
<i>Replicon#1:</i> pWNVII-Rep-G/Z; a WNV lineage II replicon expressing GFP and zocoin resistance	Pierson et al., Virology. 2006 Mar 1;346(1):53-65. (PMID: 16325883)
<i>Replicon#2:</i> pWNVII-Rep-Ren-IB; a WNV lineage II replicon expressing Renilla luciferase and blasticidin resistance	Pierson et al., Virology. 2006 Mar 1;346(1):53-65. (PMID: 16325883)

2. **THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS.** The Research Material will only be used for commercial research purposes by Recipient's Investigator in his/her laboratory, for the research project described below, under suitable containment conditions. **The Research Material will not be used in any product offered for sale or processes for the manufacture thereof, including quality control procedures, or in commercial services.**

Recipient agrees to comply with all laws, rules and regulations applicable to the Research Project and the handling of the Research Material.

- a. Is the Research Material of human origin?

Yes       No

- b. If Yes in 2a, was Research Material collected according to 45 C.F.R. Part 46, "Protection of Human Subjects"?

Yes      Please provide Assurance Number: \_\_\_\_\_  
 No

3. This Research Material will be used by Recipient's Investigator solely in connection with the following research project ("Research Project") described with specificity as follows:

**The Recipient's use of the Research Material will be limited to the scope of BARDA Contract No. HHSO100201600029C as it pertains to neutralization assays for further development of Licensee's proprietary mRNA vaccine(s) specifically directed against Zika viruses.**

Proprietary Info

Proprietary Info

4. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's contribution of this Research Material unless requested otherwise.
5. This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient therefore agrees that Recipient's Investigator will retain control over this Research Material and further agrees that Recipient's Investigator will not transfer the Research Material to other people not under her or his supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. **If the Recipient depletes its supply of Research Material or destroys the Research Material pursuant to Paragraph 12, Recipient will so notify Provider in writing.**
6. This Research Material is provided as a service to the research community. **IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.
7. Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. Recipient agrees not to claim, infer, or imply governmental endorsement of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s). Each Party shall be responsible for its own negligence under this MTA. Unless prohibited by law from doing so, Recipient agrees to hold the United States Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of any third party claim or suit in connection Recipient's use for any purpose of the Research Material, except to the extent that any such liability, demand, damage, expense or loss is attributable to Provider's negligence.
8. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.
9. This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.
10. In the event that Recipient wishes to use the Research Material for commercial purposes other than the commercial research described in Paragraph 3 above, Recipient agrees to first obtain from NIH the appropriate commercial use or commercialization authorization.
11. The provisions of Paragraphs 4, 5, 7, 9, 10, 11 and 12 of this MTA will survive expiration or termination.
12. This MTA may be executed in counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument. **This MTA will be effective when executed by the duly authorized signatories below.** Provider has previously provided materials to Recipient under separate materials transfer agreements (MTAs 2017-1210, 2017-1210-1, 2017-1210-2, 2017-0993, 2017-0993-1 and 2017-0993-2). Upon execution, these prior MTAs will be automatically terminated (if not already expired) and this MTA 2018-0664 will govern the use of the Research Material. **When the commercial license associated with the license application having NIH reference number A-261-2018 expires, is cancelled or is terminated, this MTA will be automatically terminated. The Research Material including known functional components or subunits**

**and modified/unmodified descendants, will be destroyed by the Recipient within thirty (30) days of termination or cancellation of this MTA. A facsimile, scanned electronic signature or certified electronic signature shall be as effective as an original signature.**

13. The Research Material will be used for the Research Project described in Article 3 only. The Research Material will not be used in research projects:

- (a) involving collaboration with another for-profit organization;
- (b) sponsored or funded by another for-profit organization;
- (c) in which Recipient or Recipient's Investigator is obligated to assign inventions containing the Research Material or offer an exclusive license to inventions containing the Research Material to an organization other than Recipient or a contractor of Recipient that manages Recipient's inventions on behalf of Recipient; or
- (d) in which Recipient or Recipient's Investigator is obligated to receive permission from an organization other than Recipient before publicly disclosing results of research involving the Research Material.

**NOTE:** If Recipient wishes to use the Research Material in a research project that is forbidden above, Recipient should contact the Technology Transfer and Intellectual Property Office (TTIPO), National Institute of Allergy and Infectious Diseases (NIAID), to discuss whether permission to use the Research Material in such project can be obtained.

**SIGNATURES BEGIN ON NEXT PAGE**

**MATERIAL TRANSFER AGREEMENT**

**SIGNATURE PAGE**

**FOR RECIPIENT:**

Recipient's Investigator

Kapil Bahl  
Signature

Kapil Bahl, PhD  
Senior Scientist, Infectious Disease

Date: 8/16/18

Mailing Address for Materials:

Moderna  
500 Technology Square  
Cambridge, MA 02139  
Attn: Brooke Bollman

Tel: (617) 209-5855  
Email: kapil.bahl@modernatx.com

Duly Authorized

Daphne M. Van de Meerssche  
Signature

Daphne M. Van de Meerssche, Counsel  
Printed Name and Title

Date: 8/31/18

Mailing Address for Notices:

Moderna Therapeutics  
200 Technology Square, 6th Fl.

Tel: 67-719-6500 Fax: 617-583-1998

Attn: General Counsel  
Cambridge, MA 02139

**FOR PROVIDER:**

Duly Authorized

Benjamin E. Hurley - Dig. Info. signed by Benjamin E. Hurley - 5  
Date: 2018.08.10 17:43:37 -0400

Benjamin Hurley  
TTPS, Technology Transfer and Intellectual Property  
Office NIAID

Date: August 10, 2018

Mailing Address for Notices:

TECHNOLOGY TRANSFER AND INTELLECTUAL  
PROPERTY OFFICE  
NIAID, NIH  
Suite 6D, MSC 9804  
5601 Fishers Lane  
Rockville, MD 20852  
301-496-2644 (Office)

Tel: 301/496-2644

Fax: 301/402-7123



PUBLIC HEALTH SERVICE

MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement ("MTA") has been adopted for use by the National Institutes of Health, the Food and Drug Administration and the Centers for Disease Control and Prevention, collectively referred to herein as the Public Health Service ("PHS") in all transfers of research material (Research Material) whether PHS is identified below as its Provider or Recipient.

Providers: *National Institute of Allergy and Infectious Diseases, National Institutes of Health ("NIAID")*  
ModernaTX, Inc ("Moderna")

Recipient: The University of North Carolina at Chapel Hill

1. Provider agrees to transfer to Recipient's Investigator the following Research Material:

mRNA coronavirus vaccine candidates developed and jointly-owned by NIAID and Moderna

2. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. The Research Material will only be used for research purposes by Recipient's Investigator in his/her laboratory, for the research project described below, under suitable containment conditions. This Research Material will not be used for commercial purposes such as screening, production or sale, for which a commercialization license may be required. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

- a. Are the Research Materials of human origin?

Yes  No

- b. If Yes in 2a, were Research Materials collected according to 45 CFR Part 46, "Protection of Human Subjects"?

Yes Please provide Assurance Number: \_\_\_\_\_  
 No

3. This Research Material will be used by Recipient's Investigator solely in connection with the following research project ("Research Project") described with specificity as follows (use an attachment page if necessary):

Perform challenge studies with the mRNA vaccine in a Proprietary Info model as described on Exhibit A.

4. Upon a Provider's reasonable request, Recipient will furnish a status report to such Provider regarding the use of the Research Materials and any data or results generated therefore. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Providers' contribution of this Research Material unless requested otherwise. To the extent permitted by law, Recipient agrees to treat in confidence, and not to disclose to third parties or use for any purpose other than the performance of the Research Project, for a period of three (3) years from the date of its disclosure, any of Providers' written information about this Research Material that is stamped "CONFIDENTIAL," except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from Providers to Recipient shall be identified as being CONFIDENTIAL by notice delivered to Recipient within ten (10) days after the date of the oral disclosure. Notwithstanding the foregoing, all information disclosed by Providers relating to Proprietary Info Proprietary Info of the Research Material will be treated as CONFIDENTIAL information as set forth above, whether or not marked or otherwise identified as "confidential." Recipient may publish or otherwise

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PHS MTA, Model 951214

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publicly disclose the results of the Research Project, but if Providers have given CONFIDENTIAL information to Recipient such public disclosure may be made only after Providers have had thirty (30) days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information, except when a shortened time period under court order, law (including the North Carolina Public Records Act), or the Freedom of Information Act pertains. Recipient will comply with all requests to delete CONFIDENTIAL information from any proposed publication or presentation; provided, that Providers agree to allow use of sufficient information regarding the identity and properties of the Research Material to reasonably enable publication of the results of the Research Project.

5. This Research Material represents a significant investment on the part of Providers and is considered proprietary to Providers. Recipient's Investigator therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under her or his direct supervision without advance written approval of Provider. Providers reserve the right to distribute the Research Material to others and to use it for their own purposes. When the Research Project is completed or three (3) years have elapsed, whichever occurs first, the Research Material will be disposed of as directed by Providers.
6. This Research Material is provided as a service to the research community. **IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.
7. Inventorship of any inventions or discoveries arising from the use of the Research Material hereunder ("Inventions"), shall be determined according to U.S. patent law. Ownership shall follow inventorship. Recipient will promptly disclose to Moderna in writing any Inventions. Proprietary Info  
Proprietary Info  
Proprietary Info Unless prohibited by law from doing so, including the North Carolina Tort Claims Act, Recipient agrees to hold the United States Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of Recipient's use for any purpose of the Research Material.
8. The undersigned Providers and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.
9. This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

SIGNATURES BEGIN ON NEXT PAGE

**MATERIAL TRANSFER AGREEMENT  
SIGNATURE PAGE**

**FOR RECIPIENT:**

*Recipient's Investigator*



\_\_\_\_\_  
Ralph Baric, PhD  
Professor

Date: 12/12/2019

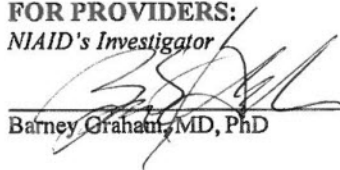
Mailing Address for Materials:

\_\_\_\_\_  
Attention: Dr. Rachel Graham, Department of  
Epidemiology, University of North Carolina at  
Chapel Hill, 135 Dauer Drive, 2101 McGavran-  
Greenberg Hall, CB #7435, Chapel Hill, NC 27599-  
7435

Tel: 919-966-3895 Fax: \_\_\_\_\_

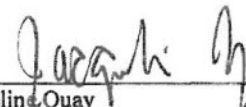
**FOR PROVIDERS:**

*NIAID's Investigator*

  
\_\_\_\_\_  
Barney Graham, MD, PhD

Date: \_\_\_\_\_

*Duly Authorized*

  
\_\_\_\_\_  
Jacquelin Quay  
Director, Licensing & Innovation Support, OTC

Date: 12/16/19

Mailing Address for Notices:

The University of North Carolina at Chapel Hill  
Office of Technology Commercialization  
109 Church Street, Chapel Hill, NC 27516

Tel: 919-966-3929 Fax: 919-962-0646

*Duly Authorized*

Amy F.  
\_\_\_\_\_  
Petrik-S  
Amy Petrik, PhD  
Technology Transfer Specialist, TTIPO, NIAID

Digitally signed by Amy  
F. Petrik -S  
Date: 2019.12.12  
08:05:22 -05'00'

Date: \_\_\_\_\_

Mailing Address for Notices:

Technology Transfer and Intellectual Property Office  
National Institute of Allergy and Infectious Diseases  
Department of Health and Human Services  
Suite 6D, MSC 9804  
5601 Fishers Lane  
Rockville, MD 20852  
Tel: 301/496-2644 Fax: 240-627-3117

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NIAID Provider  
NIAID Ref. No. 2019-1177

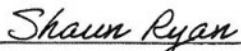
PHS MTA, Model 951214  
Page 3 of 5

*Moderna's Investigator*

  
\_\_\_\_\_  
Sunny Himansu, PhD

Date: 12/17/2019

*Duly Authorized*

  
\_\_\_\_\_  
Shaun Ryan  
Deputy General Counsel

Date: 12/17/19

Mailing Address for Notices:

ModernaTX, Inc.  
200 Technology Square  
Cambridge, MA 20139  
Attn: General Counsel

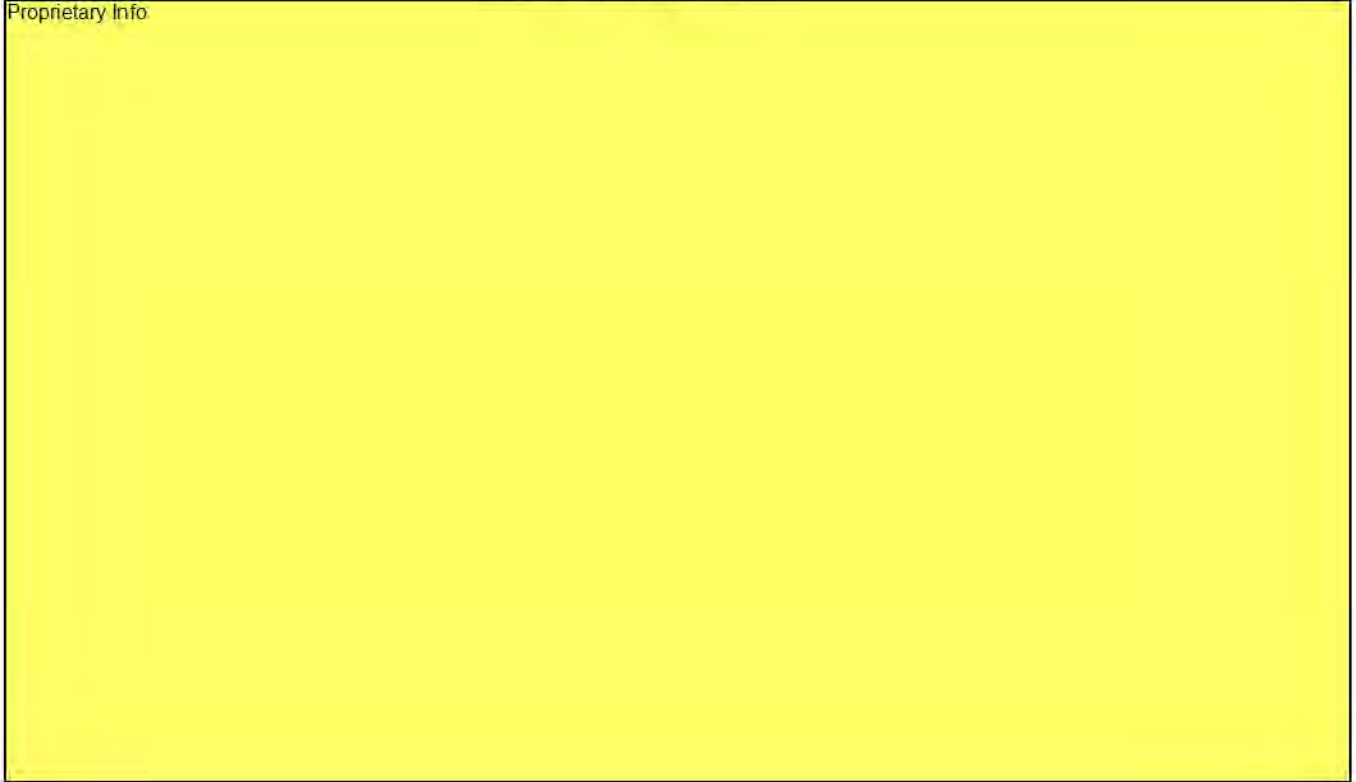
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NIAID Provider  
NIAID Ref. No. 2019-1177

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Page 4 of 5

Exhibit A  
Research Program

Proprietary Info



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NIAID Provider  
NIAID Ref. No. 2019-1177

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# **PUBLIC HEALTH SERVICE**

## **NON-EXCLUSIVE PATENT LICENSE AGREEMENT FOR INTERNAL RESEARCH USE**

*and*

## **BIOLOGICAL MATERIALS LICENSE AGREEMENT - *Internal 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  
National Institute of Allergy and Infectious Diseases  
an Institute or Center (hereinafter referred to as the "NIAID") of the  
**NIH**

and

ModernaTX, Inc.,  
hereinafter referred to as the "Licensee",  
having offices at 320 Bent Street 3<sup>rd</sup> Floor, Cambridge, MA 02141,  
created and operating under the laws of Delaware.  
Tax ID No.: 27-0226313

A-003-2018

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NIH Patent License Agreement — Internal Use Only Nonexclusive

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For NIAID's internal use only:

License Number: L-044-2018/0

License Application Number: A-003-2018

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

- I. U.S. Provisional Application 62/096,744 filed 12/24/2014 entitled "Recombinant Metapneumovirus F Proteins and Their Use" [HHS Ref. No. E-260-2014/0-US-01]
- II. PCT Patent Application PCT/IB2015/059991 filed 12/24/2015 entitled "Recombinant Metapneumovirus F Proteins and Their Use" [HHS Ref. No. E-260-2014/0-PCT-02]
- III. U.S. Patent Application 15/539,640 filed 06/23/2017 entitled "Recombinant Metapneumovirus F Proteins and Their Use" [HHS Ref. No. E-260-2014/0-US-04]
- IV. U.S. Provisional Application 62/412,699 filed 10/25/2016 entitled "Recombinant Parainfluenza Virus F Proteins and Their Use" [HHS Ref. No. E-215-2016/0-US-01]
- V. U.S. Provisional Application 61/780,910 filed 03/13/2013 entitled "Prefusion RSV F Proteins and Their Use" [HHS Ref. No. E-081-2013/0-US-01]
- VI. U.S. Provisional Application 61/798,389 filed 03/15/2013 entitled "Prefusion RSV F Proteins and Their Use" [HHS Ref. No. E-081-2013/1-US-01]
- VII. U.S. Provisional Application 61/857,613 filed 07/23/2013 entitled "Prefusion RSV F Proteins and Their Use" [HHS Ref. No. E-081-2013/2-US-01]
- VIII. U.S. Provisional Application 61/863,909 filed 08/09/2013 entitled "Prefusion RSV F Proteins and Their Use" [HHS Ref. No. E-081-2013/3-US-01]
- IX. PCT Patent Application PCT/US2014/026714 filed 03/13/2014 entitled "Prefusion RSV F Proteins and Their Use" [HHS Ref. No. E-081-2013/4-PCT-01]
- X. U.S. Patent Application 14/207,372 issued 08/22/2017 entitled "Prefusion RSV F Proteins and Their Use" [HHS Ref. No. E-081-2013/5-US-01]
- XI. U.S. Patent Application 14/776,651 filed 09/14/2015 entitled "Prefusion RSV F Proteins and Their Use" [HHS Ref. No. E-081-2013/4-US-12]
- XII. U.S. Patent Application 15/633,578 filed 06/26/2017 entitled "Prefusion RSV F Proteins and Their Use" [HHS Ref. No. E-081-2013/5-US-12]

A-003-2018

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NIH Patent License Agreement — Internal Use Only Nonexclusive  
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Cooperative Research and Development Agreement (CRADA) Number (if a subject invention): N/A

Additional Remarks:

Public Benefit(s): Proprietary Info

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 Materials, Processes, Territory, Field of Use and Term), Appendix C (Royalties), Appendix D (Shipping Information) and Appendix E (Royalty Payment Options).

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NIH Patent License Agreement — Internal Use Only Nonexclusive

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The NIAID and the Licensee agree as follows:

1. **BACKGROUND**

- 1.1 In the course of conducting biomedical and behavioral research, the NIAID investigators made inventions and developed tangible materials that may have commercial applicability.
- 1.2 By assignment of rights from the NIAID 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 NIAID, regardless of whether patents or patent applications claiming the tangible materials exist.
- 1.3 The Secretary of HHS has delegated to the NIAID 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 NIAID desires to transfer these inventions and tangible materials 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 and tangible materials 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 Additional Documentation" means information relating to the materials, owned or controlled by the NIAID inventors' laboratory, including but not limited to, protocols, analytical procedures, processes, formulas, clinical and non-clinical data, purification methods, scale up experience, alternate cell growth platforms, media development, alternate formulations, know-how, Proprietary Info [redacted] and which during the term of this Agreement (i) are in the possession or control of NIAID, and (ii) are necessary or useful to Licensee in the Licensed Fields of Use, including without limitation, in connection with the research, development, manufacture, or use of Licensed Products in the Licensed Territory.
- 2.4 "Licensed Patent Rights" shall mean:

A-003-2018

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- (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 2.4(a):
  - (i) continuations-in-part of 2.4(a);
  - (ii) all divisions and continuations of these continuations-in-part;
  - (iii) all patents issuing from these continuations-in-part, divisions, and continuations; and
  - (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 2.4(a): all counterpart foreign applications and patents to 2.4(a) and 2.4(b), including those listed in Appendix A; and
- (d) **Licensed Patent Rights** shall *not* include 2.4(b) or 2.4(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 2.4(a).

2.5 **“Licensed Products”**

- (a) means tangible materials, identified in Appendix B, including progeny, subclones, unmodified derivatives, fractions, or components isolated therefrom, whether or not within the scope of the claims of the **Licensed Patent Rights**;
- (b) other tangible materials 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;
- (c) modifications created by Licensee that contain or incorporate any of the tangible materials identified in Paragraph 2.4(a) and 2.4(b) above.

2.6 **“Licensed Processes”** means processes 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.

2.7 **“Licensed Territory”** means the geographical area identified in Appendix B.

2.8 **“Licensed Fields of Use”** means the field of use identified in Appendix B.

3. GRANT OF RIGHTS

- 3.1 The NIAID hereby grants and the Licensee accepts, subject to the terms and conditions of this Agreement, a nonexclusive license under the Licensed Patent Rights, under the Licensed Products and under certain Licensed Additional Documentation in the Licensed Territory to make and to use, but not to sell Licensed Products and Licensed Processes in the Licensed Fields of Use. Proprietary Info

Proprietary Info

- 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 NIAID other than the Licensed Patent Rights regardless of whether such patents are dominant or subordinate to the Licensed Patent Rights.
- 3.4 The NIAID acknowledges that information relating to the Licensed Patent Rights or Licensed Products may be of assistance to the Licensee in its research efforts. Accordingly, the NIAID shall consider reasonable requests by the Licensee for access to the inventors of the Licensed Patent Rights and Licensed Products. For clarity, the NIAID hereby agrees to share with the Licensee the sequences, as available, to the tangible materials identified in Section I, (c) – (f) of Appendix B, which sequences constitute Licensed Additional Documentation.

4. ROYALTIES

- 4.1 The Licensee agrees to pay the NIAID a non-creditable, nonrefundable license issue royalty as set forth in Appendix C.
- 4.2 The Licensee agrees to pay the NIAID a nonrefundable annual royalty as set forth in Appendix C.
- 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 NIAID 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 NIAID of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the NIAID from exercising any other rights it may have as a consequence of the lateness of any payment.

A-003-2018

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NIH Patent License Agreement — Internal Use Only Nonexclusive

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5. PERFORMANCE

- 5.1 Upon receipt and verification of the royalties due under Paragraphs 4.1 and 4.2, the NIAID agrees, if available to the NIAID, to provide the Licensee, at the Licensee's expense, with samples of the tangible materials identified in Appendix B 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 NIAID also agrees to make reasonable efforts to provide the Licensee with the Licensed Additional Documentation set forth in Paragraph 3.4 hereof. The Licensee agrees to retain control over the Licensed Products and Licensed Additional Documentation and shall not distribute or release them to others without the prior written consent of the NIAID. Proprietary Info  
Proprietary Info
- 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.
- 5.3 The Licensee agrees in its use of any Licensed Products provided by the NIAID 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 NIAID, in writing, of this research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the NIAID 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 NIAID 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.

6. NEGATION OF WARRANTIES AND INDEMNIFICATION

- 6.1 The NIAID offers no warranties other than those expressly specified in Article 1.
- 6.2 The NIAID 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 NIAID 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 **LICENSED ADDITIONAL DOCUMENTATION** OR OF ANY **LICENSED PRODUCTS** PROVIDED TO THE LICENSEE UNDER PARAGRAPH 5.1.
- 6.4 The NIAID 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 NIAID, 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 **Licensed Additional Documentation**; 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 NIAID may terminate this Agreement by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.
- 7.3 The NIAID 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** or **Licensed Products** 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 NIAID 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 NIAID sixty (60) days written notice to that effect.
- 7.6 Within thirty (30) days of receipt of written notice of the NIAID'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 NIAID official. The decision of the designated NIAID 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 NIAID 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 NIAID 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 NIAID or provide the NIAID with written certification of the destruction thereof.
  - (c) If the term of the Agreement is extended at the Licensee's request, then the NIAID 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 **NIAID** may request a status update report after the fifth (5<sup>th</sup>) year of the **Agreement**; and
  - (e) The **Licensee** may not be granted additional **NIAID** 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 **Licensed Products**, and the **Licensed Additional Documentation**, 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 **NIAID**. 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 **NIAID** 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 **NIAID** 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 **NIAID**'s sole option, be considered by the **NIAID** 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 **NIAID** within sixty (60) days from the date of the **NIAID** signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

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NIH NON-EXCLUSIVE PATENT LICENSE AGREEMENT  
FOR INTERNAL RESEARCH USE

FOR NIAID:

by: Michael R. Mowatt  
Michael R. Mowatt, Ph.D.  
Director  
Technology Transfer and Intellectual Property Office  
National Institute of Allergy and Infectious Diseases

23 JAN 2018  
Date

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: Giuseppe Ciaramella  
Giuseppe Ciaramella

01-16-2018  
Date

GIUSEPPE CIARAMELLA  
Printed Name

Chief Scientific Officer, Infectious Disease  
Title

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

Shaun Ryan  
Name

Deputy General Counsel  
Title

Mailing Address

A-003-2018

320 Bent Street 3<sup>rd</sup> Floor

Cambridge, MA 02141

Email Address: shaun.ryan@modernatx.com \_\_\_\_\_

Phone: 617-209-5832 \_\_\_\_\_

Fax: 617-228-7970 \_\_\_\_\_

II. Official and Mailing Address for Financial notices (Licensee's contact person for royalty payments)

Richard Wanstall

Name

Head of Audit & Finance Operations

Title

Mailing Address:

320 Bent Street 3<sup>rd</sup> Floor

Cambridge, MA 02141

Email Address: rick.wanstall@modernatx.com \_\_\_\_\_

Phone: 617-209-5860 \_\_\_\_\_

Fax: 617-225-7970 \_\_\_\_\_

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).

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

### **Patent(s) or Patent Application(s):**

- I. U.S. Provisional Application 62/096,744 filed 12/24/2014 entitled “Recombinant Metapneumovirus F Proteins and Their Use” [HHS Ref. No. E-260-2014/0-US-01]
- II. PCT Patent Application PCT/IB2015/059991 filed 12/24/2015 entitled “Recombinant Metapneumovirus F Proteins and Their Use” [HHS Ref. No. E-260-2014/0-PCT-02]
- III. U.S. Patent Application 15/539,640 filed 06/23/2017 entitled “Recombinant Metapneumovirus F Proteins and Their Use” [HHS Ref. No. E-260-2014/0-US-04]
- IV. U.S. Provisional Application 62/412,699 filed 10/25/2016 entitled “Recombinant Parainfluenza Virus F Proteins and Their Use” [HHS Ref. No. E-215-2016/0-US-01]
- V. U.S. Provisional Application 61/780,910 filed 03/13/2013 entitled “Prefusion RSV F Proteins and Their Use” [HHS Ref. No. E-081-2013/0-US-01]
- VI. U.S. Provisional Application 61/798,389 filed 03/15/2013 entitled “Prefusion RSV F Proteins and Their Use” [HHS Ref. No. E-081-2013/1-US-01]
- VII. U.S. Provisional Application 61/857,613 filed 07/23/2013 entitled “Prefusion RSV F Proteins and Their Use” [HHS Ref. No. E-081-2013/2-US-01]
- VIII. U.S. Provisional Application 61/863,909 filed 08/09/2013 entitled “Prefusion RSV F Proteins and Their Use” [HHS Ref. No. E-081-2013/3-US-01]
- IX. PCT Patent Application PCT/US2014/026714 filed 03/13/2014 entitled “Prefusion RSV F Proteins and Their Use” [HHS Ref. No. E-081-2013/4-PCT-01]
- X. U.S. Patent Application 14/207,372 issued 08/22/2017 entitled “Prefusion RSV F Proteins and Their Use” [HHS Ref. No. E-081-2013/5-US-01]
- XI. U.S. Patent Application 14/776,651 filed 09/14/2015 entitled “Prefusion RSV F Proteins and Their Use” [HHS Ref. No. E-081-2013/4-US-12]
- XII. U.S. Patent Application 15/633,578 filed 06/26/2017 entitled “Prefusion RSV F Proteins and Their Use” [HHS Ref. No. E-081-2013/5-US-12]

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

**I. Tangible Materials:**

- (a) Five hundred micrograms (500ug) of pre fusion HMPV monomer
- (b) Five hundred micrograms (500ug) of pre fusion RSV trimer
- (c) Five hundred micrograms (500ug) of pre fusion HMPV trimer
- (d) Five hundred micrograms (500ug) of post fusion HMPV trimer
- (e) Five hundred micrograms (500ug) of pre fusion PIV3 trimer
- (f) Five hundred micrograms (500ug) of post fusion PIV3 trimer

**II. Licensed Territory:**

- (a) Research facilities of Licensee and of its third party contractors in the United States of America

**III. Licensed Fields of Use (Tangible Materials (a)-(b)):**

- (a) The use of the **Licensed Products, Licensed Processes, Licensed Additional Documentation, and Licensed Patent Rights** as reagents Proprietary Info  
Proprietary

**IV. Licensed Fields of Use (Tangible Materials (c)-(f)):**

- (a) The use of the **Licensed Products, Licensed Processes, Licensed Additional Documentation, and Licensed Patent Rights** Proprietary Info  
Proprietary Info

**V. Licensed Fields of Use (sequences to Tangible Materials (c)-(f))**

- (a) The use of the **Licensed Products, Licensed Processes, Licensed Additional Documentation and Licensed Patent Rights** to Proprietary Info  
Proprietary Info

**VI. Term:**

- (a) This Agreement shall expire nine (9) years from the effective date as defined in Paragraph 7.1 unless previously terminated under Article 7.

## APPENDIX C – ROYALTIES

### **Royalties:**

- I. The Licensee agrees to pay to the NIAID a noncreditable, nonrefundable license issue royalty in the amount of Proprietary Info within sixty (60) days from the effective date of this Agreement.
  
- II. The Licensee agrees to pay to the NIAID a nonrefundable annual royalty in the amount of Propri  
Proprietary Info 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:

Samantha Calabrese \_\_\_\_\_ Research Associate \_\_\_\_\_  
Shipping Contact's Name Title

Phone: (617) 301-2492 \_\_\_\_\_ Fax: (617) 583-1998 \_\_\_\_\_ E-mail:  
Samantha.calabrese@modernatx.com \_\_\_\_\_

**Shipping Address:** Name & Address to which Materials should be shipped (please be specific):

Moderna Therapeutics, Infectious Disease \_\_\_\_\_  
Company Name & Department

Address:

500 Technology Square \_\_\_\_\_

Basement-Moderna Shipping Room \_\_\_\_\_

Cambridge, MA 02139 \_\_\_\_\_

The Licensee's shipping carrier and account number to be used for shipping purposes:

FedEx: Proprietary Info \_\_\_\_\_

## **APPENDIX E – 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”

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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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# **PUBLIC HEALTH SERVICE**

## **Amendment**

This Agreement is based on the model Amendment 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  
National Institute of Allergy and Infectious Diseases  
an Institute or Center (hereinafter referred to as the "IC") of the  
**NIH**

and

ModernaTX, Inc.,  
hereinafter referred to as the "Licensee",  
having offices at 200 Technology Square, Cambridge, MA 02139,  
created and operating under the laws of Delaware.  
Tax ID No.: 27-0226313

**FIRST AMENDMENT TO L-044-2018/0**

This is the First amendment ("First Amendment") of the agreement by and between the IC and Licensee having an effective date of 23 January 2018 and having IC Reference Number L-044-2018/0 ("Agreement"). This First Amendment, having IC Reference Number L-044-2018/1 includes, in addition to the amendments made below, 1) a Signature Page, 2) Attachment 1 (Shipping Information) and 3) Attachment 2 (Royalty Payment Information).

WHEREAS, the IC and the Licensee desire that the Agreement be amended a first time as set forth below in order to include additional tangible materials.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, the IC and the Licensee, intending to be bound, hereby mutually agree to the following:

- 1) Amend section I of Appendix B to include an additional one milligram (1mg) of prefusion RSV F trimer protein
- 2) Upon receipt by NIAID of the license amendment royalty and verification of this royalty, NIAID agrees to provide the above-named tangible materials, as available, and to replace these tangible materials, as available, at reasonable cost, to the Licensee in the event of their unintentional destruction.
- 3) Within sixty (60) days of the execution of this First Amendment, the Licensee shall pay the IC an amendment issue royalty in the sum of Proprietary Info, and payment options may be found in Attachment 2.
- 4) In the event any provision(s) of the Agreement is/are inconsistent with Attachment 1 and/or 2, such provision(s) is/are hereby amended to the extent required to avoid such inconsistency and to give effect to the shipping and payment information in such Attachment 1 and/or 2.
- 5) All terms and conditions of the Agreement not herein amended remain binding and in effect.
- 6) The terms and conditions of this First Amendment 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 First Amendment, and the First Amendment itself, to be null and void, unless this First Amendment 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's signature found at the Signature Page.
- 7) This First Amendment is effective upon execution by all parties.

**SIGNATURES BEGIN ON NEXT PAGE**

**FIRST AMENDMENT TO L-040-2018/0**

**SIGNATURE PAGE**

In Witness Whereof, the parties have executed this **First Amendment** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For the IC:

Michael R. Mowatt  
Michael R. Mowatt, Ph.D.  
Director  
Technology Transfer and Intellectual Property Office  
National Institutes of Health

29 Oct 2019  
Date

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.):

Sachin Mani  
Signature of Authorized Official

30 Oct 2019  
Date

Name: Sachin Mani  
Title: Director, Biomarkers & Assays, Infectious Disease Research

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

Shaun Ryan  
Name

Deputy General Counsel  
Title

Mailing Address:

A-020-2020

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First Amendment of L-044-2018/0  
Model 10-2015

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October 22, 2019

200 Technology Square

Cambridge, MA 02139

Email Address: shaun.ryan@modernatx.com

Phone: 617-714-6500

Fax: 617-583-1998

II. Official and Mailing Address for Financial notices (the Licensee's contact person for royalty payments):

Jennifer Lee

Name

Chief Accounting Officer

Title

Mailing Address:

200 Technology Square

Cambridge, MA 02139

Email Address: Jennifer.lee@modernatx.com

Phone: 617-714-6500

Fax: 617-583-1998

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).

**ATTACHMENT 1 – SHIPPING INFORMATION**

**The Licensee's Shipping Contact:** information or questions regarding shipping should be directed to the Licensee's Shipping Contact at:

Sachin Mani Director, Biomarkers & Assays, Infectious Disease Research  
Shipping Contact's Name Title

Phone: (617) 852-4565 Fax: (617) 583-1998 E-mail: Sachin.mani@modernaTX.com

**Shipping Address:** Name & Address to which Materials should be shipped (please be specific):

ModernaTX, Inc., Infectious Disease Research  
Company Name & Department

Address:

500 Technology Drive

Basement – Moderna Shipping Room

Cambridge, MA 02139

The Licensee's shipping carrier and account number to be used for shipping purposes:

FedEx: 127394610

**ATTACHMENT 2 – ROYALTY PAYMENT INFORMATION**

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	<b>1000</b>
{2000}	Amount	<i>(enter payment amount)</i>
{3400}	Receiver ABA routing number*	<b>021030004</b>
{3400}	Receiver ABA short name	<b>TREAS NYC</b>
{3600}	Business Function Code	<b>CTR (or CTP)</b>
{4200}	Beneficiary Identifier (account number)	<i>(enter 12 digit gateway account #)</i> <b>875080031006</b>
{4200}	Beneficiary Name	<i>(enter agency name associated with the Beneficiary Identifier)</i> <b>DHHS / NIH (75080031)</b>
{5000}	Originator	<i>(enter the name of the originator of the payment)</i> <b>COMPANY NAME</b>
{6000}	Originator to Beneficiary Information – Line 1	<i>(enter information to identify the purpose of the payment)</i> <b>ROYALTY</b>
{6000}	Originator to Beneficiary Information – Line 2	<i>(enter information to identify the purpose of the payment)</i> <b>LICENSE NUMBER</b>
{6000}	Originator to Beneficiary Information – Line 3	<i>(enter information to identify the purpose of the payment)</i> <b>INVOICE NUMBER</b>
{6000}	Originator to Beneficiary Information – Line 4	<i>(enter information to identify the purpose of the payment)</i>

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Fedwire Field Tag	Fedwire Field Name	Required Information
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](mailto: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	<b>1000</b>
{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*	<b>021030004</b>
{3400}	Receiver ABA short name	<b>TREAS NYC</b>
{3600}	Business Function Code	<b>CTR (or CTP)</b>
{4200}	Beneficiary Identifier (account number)**	<i>(enter 12 digit gateway account #)</i> <b>875080031006</b>
{4200}	Beneficiary Name	<i>(enter agency name associated with the Beneficiary Identifier)</i> <b>DHHS / NIH (75080031)</b>
{5000}	Originator	<i>(enter the name of the originator of the payment)</i> <b>COMPANY'S NAME</b>
{6000}	Originator to Beneficiary Information – Line 1	<i>(enter information to identify the purpose of the payment)</i> <b>ROYALTY</b>
{6000}	Originator to Beneficiary Information – Line 2	<i>(enter information to identify the purpose of the payment)</i> <b>LICENSE NUMBER</b>
{6000}	Originator to Beneficiary Information – Line 3	<i>(enter information to identify the purpose of the payment)</i> <b>INVOICE NUMBER</b>
{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 – <b>SWIFT CODE: FRNYUS33</b>		

**Agency Contacts:**

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

A-020-2020

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October 22, 2019

**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



# **PUBLIC HEALTH SERVICE**

## **NON-EXCLUSIVE PATENT LICENSE AGREEMENT FOR INTERNAL RESEARCH USE**

*and*

## **BIOLOGICAL MATERIALS LICENSE AGREEMENT - *Internal 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  
National Institute of Allergy and Infectious Diseases  
an Institute or Center (hereinafter referred to as the “**NIAID**”) of the  
**NIH**

and

ModernaTX, Inc.,  
hereinafter referred to as the “**Licensee**”,  
having offices at 200 Technology Square, 6<sup>th</sup> Floor, Cambridge, MA 02139,  
created and operating under the laws of Delaware.  
**Tax ID No.: 27-0226313**

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**CONFIDENTIAL**

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

License Number:

License Application Number: A-261-2018

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

- I. U.S. Provisional Application 62/396,613 filed 09/19/2016 entitled "Zika Virus Vaccines" [HHS Ref. No. E-181-2016/0-US-01]
- II. PCT Patent Application PCT/US2017/044468 filed 07/28/2017 entitled "Zika Virus Vaccines" [HHS Ref. No. E-181-2016/0-PCT-02]

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

Additional Remarks:

Public Benefit(s): Proprietary Info for use in development of Zika vaccine(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 (tangible materials, Licensed Territory, Licensed Field of Use and Term), Appendix C (Royalties) and Appendix D (Royalty Payment Options).

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The NIAID and the Licensee agree as follows:

1. **BACKGROUND**

- 1.1 In the course of conducting biomedical and behavioral research, the NIAID investigators made inventions and developed tangible materials that may have commercial applicability.
- 1.2 By assignment of rights from the NIAID 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 NIAID, regardless of whether patents or patent applications claiming the tangible materials exist.
- 1.3 The Secretary of HHS has delegated to the NIAID 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 NIAID desires to transfer these inventions and tangible materials 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 and tangible materials 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;

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

- (a) means tangible materials, identified in Appendix B, including progeny, subclones, unmodified derivatives, fractions, or components isolated therefrom, whether or not within the scope of the claims of the **Licensed Patent Rights**;
- (b) other tangible materials 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;
- (c) modifications created by Licensee that contain or incorporate any of the tangible materials identified in Paragraph 2.4(a) and 2.4(b) above.

2.5 “**Licensed Processes**” means processes 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 Field of Use**” means the field of use identified in Appendix B.

2.8 “**BARDA**” means Biomedical Advanced Research and Development Authority, part of the HHS Office of the Assistant Secretary for Preparedness and Response.

3. GRANT OF RIGHTS

3.1 The NIAID hereby grants and the Licensee accepts, subject to the terms and conditions of this Agreement, a nonexclusive license under the **Licensed Patent Rights** and under the **Licensed Products** in the **Licensed Territory** to make and to use, but not to sell **Licensed Products** and **Licensed Processes** in the **Licensed Field of Use**.

3.2 The Licensee has no right to sublicense.

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

4. ROYALTIES

- 4.1 The Licensee agrees to pay the NIAID a non-creditable, nonrefundable license issue royalty as set forth in Appendix C.
- 4.2 The Licensee agrees to pay the NIAID a nonrefundable annual royalty as set forth in Appendix C.
- 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 D. No royalties shall be paid with funds stemming from any federal contract, grant, or cooperative agreement. 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 NIAID 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 NIAID of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the NIAID from exercising any other rights it may have as a consequence of the lateness of any payment.

5. PERFORMANCE

- 5.1 NIAID has previously provided materials to Licensee under separate materials transfer agreements (NIAID Material Transfer Agreements 2017-1210, 2017-1210-1, 2017-0993 and 2017-0993-1). Upon execution, this Agreement will govern the use of Licensed Products. 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 NIAID.
- 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 NIAID 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 NIAID, in writing, of this research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the NIAID 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.

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- 5.4 All plans and reports required by this Agreement shall be treated by the NIAID 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.
- 5.5 The Licensee is encouraged to publish the results of its research projects using the **Licensed Patent Rights**, the **Licensed Products** and/or the **Licensed Processes**. In all oral presentations or written publications concerning the **Licensed Patent Rights**, the **Licensed Products** and/or the **Licensed Processes**, the Licensee shall acknowledge the contribution of Dr. Theodore Pierson, the NIAID Laboratory of Viral Diseases and NIAID as the HHS agency supplying the **Licensed Patent Rights**, the **Licensed Products** and/or the **Licensed Processes**, unless requested otherwise by the NIAID or Dr. Theodore Pierson.

6. NEGATION OF WARRANTIES AND INDEMNIFICATION

- 6.1 The NIAID offers no warranties other than those expressly specified in Article 1.
- 6.2 The NIAID 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 NIAID 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 NIAID 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 NIAID, 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.

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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 **NIAID** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.
- 7.3 The **NIAID** shall specifically have the unilateral right to terminate this **Agreement** by written notice if the **Licensee**:
- (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** or **Licensed Products** 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, in its representations made to **NIAID** in the course of establishing this **Agreement**, or in any report required by this **Agreement**.
- 7.4 The **NIAID** 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 **NIAID** sixty (60) days written notice to that effect.
- 7.6 Within thirty (30) days of receipt of written notice of the **NIAID**'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 **NIAID** official. The decision of the designated **NIAID** 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 The **NIAID** Material Transfer Agreement identified as 2018-0664 shall be terminated immediately and automatically upon expiration or termination of this **Agreement**.

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- 7.9 This Agreement and NIAID Material Transfer Agreement identified as 2018-0664 shall be terminated immediately and automatically upon cancellation, revocation or termination of **BARDA Contract No. HHSO100201600029C**. The Licensee shall alert the NIAID to the cancellation, revocation or termination or termination of **BARDA Contract No. HHSO100201600029C** within five (5) days of such occurrence.
- 7.10 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 NIAID 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 NIAID shall become immediately due and payable upon termination or expiration
  - (c) If the term of the Agreement is extended at the Licensee's request, then the NIAID and the Licensee will negotiate in good faith regarding the schedule for reports regarding the information required in 7.10(a);
  - (d) If the term of this Agreement is longer than ten (10) years, then the NIAID may request a status update report after the fifth (5<sup>th</sup>) year of the Agreement; and
  - (e) The Licensee may not be granted additional NIAID licenses if this reporting requirement is not fulfilled.
- 7.11 Within thirty (30) days of termination or expiration of this Agreement, the Licensee shall destroy all materials associated with the NIAID Material Transfer Agreement identified as 2018-0664, all **Licensed Products** and all other materials included within the **Licensed Patent Rights**, and provide the NIAID with written certification of the destruction thereof. The Licensee may not be granted additional NIAID licenses if this reporting requirement is not fulfilled.
- 7.12 Paragraphs 4.3, 4.4, 5.4, 5.5, 6.1-6.5, 7.6, 7.8, 7.9, 7.10, 7.11 and 7.12 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 Licensed Products**, 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.

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- 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 NIAID. 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 NIAID 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 NIAID 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.
- 8.8 The terms and conditions of this Agreement shall, at the NIAID's sole option, be considered by the NIAID 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 NIAID within sixty (60) days from the date of the NIAID signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

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NON EXCLUSIVE PATENT LICENSE AGREEMENT  
FOR INTERNAL RESEARCH USE  
and  
BIOLOGICAL MATERIALS LICENSE AGREEMENT - Internal Use

FOR NIAID:

by: Michael R. Mowatt 8 AUG 2018  
Michael R. Mowatt, Ph.D. Date  
Director  
Technology Transfer and Intellectual Property Office  
National Institute of Allergy and Infectious Diseases  
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: Daphne M. Van de Meerssche Aug. 31, 2018  
Signature of Authorized Official Date

Daphne M. Van de Meerssche  
Printed Name

Counsel  
Title

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

Lori Henderson  
Name

General Counsel  
Title

Mailing Address

200 Technology Square, 6<sup>th</sup> floor

Cambridge, MA 02141

Email Address: legal@modernatx.com

Phone: 617-714-6500

Fax: 617-583-1998

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

III. The **NIAID** will invoice the **Licensee** for all amounts due hereunder and will send all invoices to the attention of "Accounts Payable" at the following email address: moderna\_invoice@conkursolutions.com.

Richard Wanstall  
Name

Head of Audit & Finance Operations  
Title

Mailing Address:

200 Technology Square, 4<sup>th</sup> floor

Cambridge, MA 02139

Email Address: rick.wanstall@modernatx.com

Phone: 617-209-5860

Fax: 617-225-7970

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).

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

**Patent(s) or Patent Application(s):**

- I. U.S. Provisional Application 62/396,613 filed 09/19/2016 entitled “Zika Virus Vaccines” [HHS Ref. No. E-181-2016/0-US-01]
- II. PCT Patent Application PCT/US2017/044468 filed 07/28/2017 entitled “Zika Virus Vaccines” [HHS Ref. No. E-181-2016/0-PCT-02]

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**APPENDIX B – TANGIBLE MATERIALS, LICENSED TERRITORY, LICENSED FIELD OF USE AND TERM**

**I. Tangible Materials:**

- (a) pZIKV-H/PF/2013-CprME; a DNA expression construct expressing C-prM-E structural genes of ZIKV strain H/PF2013
- (b) pDENV1-WestPac-CprME; DNA expression construct expressing C-prM-E structural genes of DENV strain Western Pacific
- (c) pDENV2-16681-CprME; a DNA expression construct expressing C-prM-E structural genes of DENV strain 16681

**II. Licensed Territory:**

Research facilities of Licensee located in the United States of America

**III. Licensed Field of Use:**

The use of the **Licensed Products, Licensed Processes, and Licensed Patent Rights** limited to the scope of BARDA Contract No. HHSO100201600029C as it pertains to **Proprietary Info** for further development of Licensee's proprietary mRNA vaccine(s) specifically directed against Zika viruses. For the sake of clarity, the **Licensed Field of Use** specifically excludes the use of **Licensed Products, Licensed Processes, and Licensed Patent Rights** in **Proprietary Info** non-Zika virus vaccines, as well as DNA-based Zika vaccines expressing virus-like particle antigens.

**IV. Term:**

- (a) This **Agreement** shall expire August 27, 2020, the end of the period of performance for **BARDA** Contract No. HHSO100201600029C, unless previously terminated under Article 7.

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## APPENDIX C – ROYALTIES

### **Royalties:**

- I. The Licensee agrees that the **Licensed Products, Licensed Processes, and Licensed Patent Rights** represent a significant investment on the part of the **NIAID**, and that the **Licensed Products, Licensed Processes, and Licensed Patent Rights** are of substantial value. Notwithstanding the foregoing, the **NIAID** hereby grants to the Licensee a royalty-free, non-exclusive license, subject to the terms and conditions of this **Agreement**, due to the research support of **BARDA** Contract No. **HHSO100201600029C**.

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**APPENDIX D- 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	<b>1000</b>
{2000}	Amount	<i>(enter payment amount)</i>
{3400}	Receiver ABA routing number*	<b>021030004</b>
{3400}	Receiver ABA short name	<b>TREAS NYC</b>
{3600}	Business Function Code	<b>CTR (or CTP)</b>
{4200}	Beneficiary Identifier (account number)	<i>(enter 12 digit gateway account #)</i> <b>875080031006</b>
{4200}	Beneficiary Name	<i>(enter agency name associated with the Beneficiary Identifier)</i> <b>DHHS / NIH (75080031)</b>
{5000}	Originator	<i>(enter the name of the originator of the payment)</i> <b>COMPANY NAME</b>
{6000}	Originator to Beneficiary Information – Line 1	<i>(enter information to identify the purpose of the payment)</i> <b>ROYALTY</b>
{6000}	Originator to Beneficiary Information – Line 2	<i>(enter information to identify the purpose of the payment)</i> <b>LICENSE NUMBER</b>
{6000}	Originator to Beneficiary Information – Line 3	<i>(enter information to identify the purpose of the payment)</i> <b>INVOICE NUMBER</b>

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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 33 Liberty Street, New York, NY 10045.		

**Agency Contacts:** Office of Technology Transfer (OTT) (301) 496-7057 [OTT-Royalties@mail.nih.gov](mailto: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	<b>1000</b>
{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*	<b>021030004</b>
{3400}	Receiver ABA short name	<b>TREAS NYC</b>
{3600}	Business Function Code	<b>CTR (or CTP)</b>
{4200}	Beneficiary Identifier (account number)**	<i>(enter 12 digit gateway account #)</i> <b>875080031006</b>
{4200}	Beneficiary Name	<i>(enter agency name associated with the Beneficiary Identifier)</i> <b>DHHS / NIH (75080031)</b>
{5000}	Originator	<i>(enter the name of the originator of the payment)</i> <b>COMPANY'S NAME</b>
{6000}	Originator to Beneficiary Information – Line 1	<i>(enter information to identify the purpose of the payment)</i> <b>ROYALTY</b>
{6000}	Originator to Beneficiary Information – Line 2	<i>(enter information to identify the purpose of the payment)</i> <b>LICENSE NUMBER</b>
{6000}	Originator to Beneficiary Information – Line 3	<i>(enter information to identify the purpose of the payment)</i> <b>INVOICE NUMBER</b>
{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 33 Liberty Street, New York, NY 10045. **Anything other than the 12 digit gateway account # will cause the Fedwire to be returned – SWIFT CODE: <b>FRNYUS33</b>		

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

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Government Lockbox SL-MO-C2GL  
1005 Convention Plaza  
St. Louis, MO 63101  
Phone: 314-418-4087

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