DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via E-mail: foia@americanoversight.org

July 20, 2022

Mr. Austin Evers
American Oversight
1030 15th Street, NW Ste. B255
Washington, DC 20005

Re: NIH FOIA Case No. 54020

Dear Mr. Evers,

This is the final response to your April 17, 2020, Freedom of Information Act (FOIA) request addressed to the FOIA Office, National Institutes of Allergy and Infectious Diseases (NIAID) which was received the same day. Department of Health and Human Services' (HHS) policy calls for the fullest possible disclosure provided by the FOIA, 5 U.S.C. §552, consistent with the protections contained therein. The implementing HHS Regulations establish the criteria pursuant to which the FOIA is administered, *see* 45 C.F.R. Part 5. Copies of the FOIA and the HHS FOIA Regulations are located at: http://www.nih.gov/icd/od/foia/efoia.htm and http://www.nih.gov/icd/od/foia/cfr45.htm.

You requested All communications between: NIAID Director or NIAID Principal Deputy Director or NIAID Deputy Director, Clinical Research or Director, DMID/NIAID and Fujifilm or Tamoy Chemical or Ipca Laboratories or Zydus Cadila or Cipla or Wallace Pharmaceuticals. Date Range 3/1/2020 to 4/17/2020

NIAID searched their files and located 22 pages responsive to your request, all which are enclosed. I have determined to withhold portions of the released pages pursuant to your agreement, and Exemptions 4 and 6 of the FOIA, 5 U.S.C. § 552 (b)(4) and (b)(6). The information being withheld is protected from release pursuant to Exemptions 4 and 6 of the FOIA, 5 U.S.C. § 552 (b)(4) and (b)(6); and sections 5.31(d) and (f) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential. Exemption 6 permits the withholding of privacy information, the release of which would constitute a clearly unwarranted invasion of personal privacy.

You have the right to appeal this determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart F of the HHS FOIA Regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations) to the Assistant Secretary for Public Affairs at https://requests.publiclink.hhs.gov/App/Index.aspx.

Clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

If you are not satisfied with the processing and handling of this request, you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison
Denean Standing-Ojo
Office of Communications and
Public Liaison
Building 31, 5B52S
31 Center Drive
Bethesda, MD 20892
301-496-5077 (phone)
nihfoia@mail.nih.gov (email)

OGIS
National Archives and Records Admin.
8601 Adelphi Rd – OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

In certain circumstances, provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there is no charge associated with our response.

If you have any questions about this response, please call 301-496-5633.

Sincerely,

Gorka Garcia-malene -S
Digitally signed by Gorka Garcia-malene -S
Date: 2022.07.20 16:53:10 -04'00'

Gorka Garcia-Malene
Freedom of Information Officer, NIH

Enclosures: One pdf file (total 22 pages)

From: Miers, Sarah (NIH/NIAID) [E] on behalf of Erbelding, Emily (NIH/NIAID) [E]
Sent: Fri, 22 May 2020 10:24:10 -0400
To: Miers, Sarah (NIH/NIAID) [E]
Subject: FW: Fujifilm Pharma NCEA

From: "Cassetti, Cristina (NIH/NIAID) [E]" (b) (6)
Date: Friday, May 8, 2020 at 10:14 AM
To: "Lampley, Rebecca (NIH/NIAID) [C]" (b) (6)
Cc: "Erbelding, Emily (NIH/NIAID) [E]" (b) (6) "Zeituni, Erin (NIH/NIAID) [E]" (b) (6) "Raterman, Erica (NIH/NIAID) [E]" (b) (6) "Davis, Mindy (NIH/NIAID) [E]" (b) (6)
Subject: RE: Fujifilm Pharma NCEA

I believe that this is done now

From: Robert P Lenk (b) (6)
Sent: Friday, May 8, 2020 9:51 AM
To: Lampley, Rebecca (NIH/NIAID) [C] (b) (6)
Cc: Erbelding, Emily (NIH/NIAID) [E] (b) (6) Cassetti, Cristina (NIH/NIAID) [E] (b) (6) Zeituni, Erin (NIH/NIAID) [E] (b) (6) ; Raterman, Erica (NIH/NIAID) [E] (b) (6) Davis, Mindy (NIH/NIAID) [E] (b) (6)
Subject: Re: Fujifilm Pharma NCEA

Rebecca,

A gentle reminder that we need an executed copy of the signed NCEA document for our records.
I am not sure who needs to sign this, but our attorney requires the loop be closed.

Bob

Robert P, Lenk, PhD

On May 6, 2020, at 3:55 PM, Lampley, Rebecca (NIH/NIAID) [C] (b) (6) wrote:

Hi All,

Please see Dr. Lenk's email below..

Best,
Rebecca

Rebecca M. Lampley M.S. [C]
Program Manager
Respiratory Diseases Branch
DMID/NIAID/NIH/DHHS
5601 Fishers Lane Desk 8A17
Rockville, MD 2089
Direct: (b) (6)
Cell: (b) (6)
E-mail: (b) (6)

From: Robert P Lenk (b) (6)
Sent: Wednesday, May 6, 2020 3:29 PM
To: Lampley, Rebecca (NIH/NIAID) [C] (b) (6)
Cc: Dr Brett Hurst (b) (6); Davis, Mindy (NIH/NIAID) [E] (b) (6); Eakin, Ann (NIH/NIAID) [E] (b) (6)
Subject: Re: Fully Executed: Fujifilm Pharma_Lenk SECONDARY (b) (4) SRF_SARS-CoV-2

Rebecca,

Our attorney provided me with this executed copy of the NCEA document signed by our CEO, Mikihiko Kato, for your records.
I do not have the email address of Dr. Erbelding, if you could forward.

Bob

Robert P, Lenk, PhD
President
Lenk Pharmaceuticals, LLC
(b) (6)
2345 Berry Hill Rd
Danville, VA 24541

On May 5, 2020, at 4:19 PM, Lampley, Rebecca (NIH/NIAID) [C] (b) (6) wrote:

Dr. Lenk,

Thank you for returning the EXECUTED SRF for secondary assay testing.

At this time, (b) (4) If this changes, (b) (4) will reach out to you with Dr. Mindy Davis, Dr. Ann Eakin and myself cc'ed.

Looking forward to the results!

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<Fully Executed Fujifilm (b) (4) Secondary SRF 2019-20 (b) (4) pdf>

<DMID-NCEA_2020May04_exec_copy_fphu.pdf>

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Date: Friday, May 8, 2020 at 10:04 AM
To: Robert P Lenk (b) (6)
Cc: "Erbelding, Emily (NIH/NIAID) [E]" (b) (6), "Cassetti, Cristina (NIH/NIAID) [E]" (b) (6), "Zeituni, Erin (NIH/NIAID) [E]" (b) (6), "Raterman, Erica (NIH/NIAID) [E]" (b) (6), "Davis, Mindy (NIH/NIAID) [E]" (b) (6), "Tibbals, Melinda (NIH/NIAID) [C]" (b) (6)
Subject: RE: Fujifilm Pharma NCEA

Hi Bob,

Thank you for the reminder. I have cc'd Melinda who has been coordinating the NCEA efforts. She is more aware of the status then I am so I will look to her to respond.

Hope you're doing well!

Rebecca

Rebecca M. Lampley M.S. [C]
Program Manager
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storage devices. National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are sender's own and not expressly made on behalf of the NIAID by one of its representatives.

From: Robert P Lenk (b) (6)
Sent: Wednesday, May 6, 2020 3:29 PM
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Cc: Dr Brett Hurst (b) (6); Davis, Mindy (NIH/NIAID) [E] (b) (6); Eakin, Ann (NIH/NIAID) [E] (b) (6)
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Sent: Fri, 22 May 2020 10:23:53 -0400
To: Miers, Sarah (NIH/NIAID) [E]
Subject: FW: Fujifilm Pharma NCEA
Attachments: DMID-NCEA_2020May04_exec_copy_fphu.pdf

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Subject: Fujifilm Pharma NCEA

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> **Rebecca M. Lampley M.S. [C]**
> *Program Manager*
> Respiratory Diseases Branch
> DMID/NIAID/NIH/DHHS

5601 Fishers Lane Desk 8A17
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<Fully Executed Fujifilm (b) (4) Secondary SRF 2019-20 (b) (4) April 28 2020.pdf>

NIAID Non-Clinical Evaluation Agreement

FUJIFILM Pharmaceuticals U.S.A., Inc., referred to in this NIAID Non-Clinical Evaluation Agreement ("NCEA" or "Agreement") as "Provider", has requested to utilize the non-clinical and pre-clinical services program funded by the Division of Microbiology and Infectious Diseases ("DMID"), part of the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute of the National Institutes of Health (NIH), which is a component of the Department of Health and Human Services (HHS), an agency of the U.S. Government. NIAID and Provider are each a "Party" to this Agreement, and are collectively the "Parties".

Definitions

"Confidential Information" means proprietary and confidential scientific, regulatory, business or financial information, and may include Data from Individual(s).

"Contractor(s)" means NIAID's testing laboratories or contract coordinating facilities.

"Contractor Subject Invention(s)" are inventions of the Contractor conceived or first actually reduced to practice during the performance of the Service(s).

"Class 1 Subject Invention(s)" means Contractor Subject Invention(s) that requires the use of, improves or incorporates any Provider's Material.

"Class 2 Subject Invention(s)" means Contractor Subject Invention that is a method of manufacturing or synthesis of Provider's Material.

"Data from Individuals" means data obtained through intervention or interaction with an individual (see 45 CFR 46.102(f)).

"Deliverable(s)" means data, results, plans, protocols, assessments, documentations, reports, or tangible products generated from Service(s) by Contractor(s).

"Derivatives of Human Material(s)" includes human cell lines, recombinant DNA clones of human genes, and isolated infectious agents from humans.

"Human Material(s)" includes those obtained directly from humans as well as Derivatives of Human Material(s). Those obtained directly from humans include, but are not limited to, everything from tissue (e.g., bone, muscle, and connective tissue), organs (e.g., skin, liver, bladder, heart, and kidney), blood, gametes (e.g., sperm and ova), embryos, fetal tissue, and waste (eg., urine, feces, sweat, hair and nail clippings, shed epithelial cells, placenta) as well as extracted or subcomponent parts of these materials including whole genomic DNA, plasma, protein fractions, or fractionated cells.

"Material(s)" means any proprietary material, method, product, composition, compound or device, whether patented or unpatented, which is provided by the Provider. Material(s) may include Human Material(s) or Derivatives of Human Material(s).

"Service(s)" means evaluation of Provider's Material(s) for possible activity against infectious organism(s), or non-clinical or pre-clinical analysis of Provider's Material(s) including Human Material(s) or Provider's Confidential Information.

NIAID and Provider agree as follows:

1. Submission of Material(s) or Confidential Information

Provider may request to submit without charge Provider's Material(s) to NIAID for Service(s) by Contractor(s).

Provider may request to submit Confidential Information pertaining to Provider's Material(s), intellectual property, synthesis schemes, assays, processes, animal models, or pre-clinical or clinical data to NIAID for Service(s) by Contractor(s).

1.1 While Provider may not select the Contractor(s) to be used, Provider has the right to decline the use of particular Contractor(s) conducting Service(s) or to decline to submit any Material(s) or Confidential Information to a particular Contractor. NIAID has the right to decline to conduct Service(s) of any Material(s) or Confidential Information. Provider understands that not all Service(s) offered by NIAID are available at all times.

1.2 For the duration of this Agreement, the Provider may submit one or more Material(s) or Confidential Information for Service(s). For each requested Service, Provider must complete a Service Request Form ("SRF") which when signed by both the NIAID project/program officer and the Provider project/program officer identified on the SRF is incorporated and attached as an appendix to this Agreement and subject to the terms and conditions contained herein. A program specific SRF may be obtained from the NIAID project/program officer. A sample SRF is attached as Attachment 1 to this Agreement. Service(s) of additional Material(s) or Confidential Information may be requested by submitting additional SRFs within the term of this Agreement by mutual agreement between the NIAID project/program officer and Provider project/program officer without amendment of this Agreement. Material(s) or Confidential Information submitted to NIAID for Service(s) during the effective period of this Agreement will be handled in accordance with this Agreement.

1.3 Following execution of this Agreement and approval of the SRF(s) by NIAID, in accordance with NIAID's directions, Provider will forward to Contractor(s) one or more Material(s), or Provider will forward to NIAID or Contractor(s) Confidential Information for Service(s) along with the SRF. The SRF will specify the Material(s) or Confidential Information to be evaluated.

1.4 The NIAID project/program officer may require chemical structures and pertinent data for the Service(s) related to Material(s).

1.5 **Human Material(s) or Data from Individual(s)**. *If Material(s) are Human Material(s) or if Confidential Information contains Data from Individual(s), then this article 1.5 is applicable.*

1.5.1 Provider may request to submit Human Material(s) or Derivatives of Human Material(s) for Service(s).

1.5.2 If Provider submits Human Material(s) or Data from Individual(s) for Service(s), then the Provider warrants and represents that the Human Material(s) or Data from Individual(s):

(a) Has no identifiable private information (see 45 CFR 46.102(f)) or, if coded, neither NIAID nor Contractor(s) has access nor will be provided access to the key to the code; and

(b) Was obtained consistent with the informed consent(s) signed by the donor of Human Material(s) or Data from Individual and is compliant with 45 CFR 46.116-117.

1.5.3 Provider warrants and represents that the Service(s) requested by Provider is permitted under the informed consent(s), has been approved by Provider's Institutional Review Board or equivalent, if appropriate, and is not prohibited by any applicable laws, statutes or regulations.

1.5.4 Neither NIAID nor Contractor(s) will contact or make any effort to identify individuals who are or may be the sources of Human Material(s) or Data from Individual(s).

1.5.5 Any Human Material(s) or Data from Individual(s) that is submitted to NIAID or Contractor for Service(s) with identifiable private information or a key to the code will be returned to Provider unevaluated at Provider's expense.

1.5.6 Deliverable(s) of Service(s) performed using Human Material(s) or Data from Individual(s) will not be used by Provider for any diagnostic, prognostic or treatment purposes.

1.6 Provider certifies that it has the freedom to operate for the requested Service(s). Provider will obtain any permission or acquire any requisite rights of third parties prior to submission of Material(s) or Confidential Information for Service(s) to NIAID.

2. Service(s)

2.1 Protocol(s) used for Service(s) are available upon request from NIAID.

2.2 Confidential Information and Material(s) of Provider will be used only for Service(s) as mutually agreed to by Provider and NIAID and for no other purpose. Upon completion of Service(s) all unused Material(s) will be destroyed or returned to Provider at Provider's expense.

3. Confidentiality

3.1 Provider must identify any Confidential Information in writing as "Confidential" in order for the information to be considered confidential. NIAID represents that Contractors are required by the NIAID contracts to protect such Confidential Information in accordance with this Article 3.

3.2 To the extent permitted by law, Confidential Information disclosed to NIAID or by NIAID to Contractors will remain confidential for five (5) years from the date of disclosure in accordance with Article 3.4.

3.3 Confidential Information does not include information that:

3.3.1 Is known to the public or becomes known to the public through no fault of the recipient;

3.3.2 Was obtained by the recipient, without restriction, from a third party having no confidentiality obligation to Provider;

3.3.3 Was made available to the recipient by Provider without a confidentiality obligation, or with prior written authorization for its disclosure;

3.3.4 Has been independently developed by the recipient without reference to Provider's information;

3.3.5 Is required to be disclosed by law, regulation or court order provided that Provider has been notified and the recipient has taken reasonable efforts to minimize the extent of the required disclosure; or

3.3.6 Provider expressly granted authorization to NIAID to disclose.

3.4 The period for maintaining the confidentiality of Confidential Information disclosed to NIAID in conjunction with a Service Request Form (SRF) shall start upon the date of execution (date of last signature of Provider's or NIAID's project/program officer on the SRF) of said SRF. Each SRF shall bear the statement "Confidential Information submitted and attached to this Service Request Form (SRF) shall remain confidential for five (5) years from the date of last signature of this SRF. This SRF and the Service(s) to be performed hereunder are subject to all the terms and conditions of the NIAID Non-Clinical Evaluation Agreement executed between Provider and NIAID." Any Confidential Information not submitted together and attached to a SRF must bear a date of disclosure and be identified as "Confidential" and reference this Agreement and the appropriate SRF in order for the five (5) year confidentiality term from the date of disclosure to apply, subject to Article 3.3 above.

4. Deliverable(s)

4.1 NIAID will work in conjunction with Contractor(s) to ensure timely ongoing communication of progress of Service(s).

4.2 NIAID will communicate or request shipment of Deliverable(s) to Provider within 14 days of acceptance from the Contractor(s).

4.3 None of the Deliverable(s) from the Service(s) are Provider's Confidential Information and may be disclosed by NIAID or Contractor in accordance with Articles 4.5 and 5 below. However, some information in the Deliverable(s) provided to Provider may relate to invention(s) of the Provider or to Contractor Subject Invention(s) that are required to be assigned or licensed to the Provider. Therefore, Provider should maintain such information in confidence until such time that Provider files a patent application or otherwise protects such invention(s) or Contractor Subject Invention(s).

4.4 Provider will NOT contact Contractor(s) for any Deliverable(s) from the Service(s). Provider may contact Contractor for intellectual property matters in accordance with Article 6.6 below.

4.5 Provider, NIAID or the Contractor may publish or publicly disclose the Deliverable(s) from the Service(s). A proposed publication or other public disclosure may be delayed for three (3) months to allow Provider time to file patent applications if desired in accordance with Article 5 below.

5. Publications

5.1 *Contractor's Publications.* Contractor is required to notify NIAID thirty (30) days prior to any proposed publication or public disclosure relating to work performed under the contract. NIAID will provide Provider with Contractor's proposed disclosure within seven (7) days of receipt from Contractor. Provider will have fourteen (14) days to review Contractor's proposed disclosure, and Provider will notify NIAID in writing within this fourteen (14) days review period of Provider's intent to file a patent application and to request a delay of three (3) months. The three (3) months delay period will commence on the date of notification to NIAID by Provider. NIAID will notify Contractor of Provider's request to delay within seven (7) days of notification from Provider. If no such notification is received by NIAID from Provider within such fourteen (14) day review period, the Contractor will be free to publish or disclose. NIAID and the Provider will maintain the Contractor's proposed publication or public disclosure in confidence until publication or public disclosure by Contractor.

5.2 *Provider's and NIAID's Publications.* Before Provider or NIAID publishes or publicly disclose the Deliverable(s) from the Service(s), each Party will provide the other Party fourteen (14) days to review and comment on the proposed publication or public disclosure. Provider will notify NIAID in writing within such fourteen (14) days review period of Provider's intent to file a patent application and to request a delay of NIAID's publication for three (3) months. The three (3) months period of delay will commence on the date of notification to NIAID by Provider. If no such notification is received by

NIAID within the fourteen (14) day review period, NIAID will be free to publish or disclose. The reviewing Party will maintain the proposed publication or public disclosure of the submitting Party in confidence until publication or public disclosure by the submitting Party.

5.3 Provider will not construe the involvement of NIAID in Service(s) as an endorsement of Material(s) or Confidential Information by the U.S. Government or any of its agencies, employees or Contractors. Provider will give appropriate credit for the Service(s) to NIAID and the Contractor(s) by including the following statement in all its publications related to the Service(s) *"FUJIFILM Pharmaceuticals U.S.A., Inc. will be utilizing//has utilized the non-clinical and pre-clinical services program offered by the National Institute of Allergy and Infectious Diseases."*

6. Intellectual Property

6.1 Subject to applicable law, Provider will retain all of Provider's existing intellectual property rights to Material(s).

6.2 The contracts between NIAID and the Contractor(s) performing Service(s) require the Contractor(s) to assign to the Provider the entire right, title, and interest throughout the world to each Class 1 Subject Invention(s). Any such assignment will be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the United States government to practice or have practiced Class 1 Subject Invention(s) for or on behalf of the United States throughout the world. Any such assignment shall additionally be subject to the "March-in-rights" of 35 U.S.C. 203. If the Contractor is a U.S. nonprofit educational institution it may require the Provider to allow it to retain a royalty free, nonexclusive, nontransferable license solely to practice the invention for noncommercial internal research.

6.3 For each Class 2 Subject Invention(s) the Contractor(s) is required to grant a nonexclusive, irrevocable worldwide, royalty-free license to the Provider for all research or commercial use involving Provider's Material. Provider shall have the right to grant sub-licenses to any Provider's licensee(s) or collaborator(s) to enable further research, development and commercialization of the Material.

6.4 Contractor Subject Inventions which are not Class 1 or Class 2 Subject Invention(s) are governed by the standard Federal Acquisition Regulations Patent Rights clause at FAR 52.227-11 which allows a contractor to elect to retain title to its Contractor Subject Invention(s).

6.5 Any Contractor Subject Invention(s) reported to Provider (by NIAID or Contractor(s)) will be maintained in confidence by Provider until a patent application has been filed or the Contractor Subject Invention(s) is otherwise protected or the relevant parties agree in writing that confidentiality is no longer needed to avoid a disclosure.

6.6 Provider may communicate with Contractor on legal matters related to Contractor Subject Invention(s). Provider and Contractor may negotiate separate agreements that do not conflict with this Agreement or the contract(s) NIAID has with Contractor(s).

7. No Warranty

Material(s) is experimental in nature. Provider makes no representations and extends no warranty of any kind, either expressed or implied, including any warranty of merchantability or fitness for a particular purpose.

8. Liability and Indemnification

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*.

9. 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.

10. Term of Agreement

This Agreement will be in effect for five (5) years from the date of the last authorized signature below ("Effective Date").

11. Amendments

This Agreement may be amended only by written instrument signed by authorized representative of NIAID and Provider. A written amendment is not required for the submission of additional SRF(s) in accordance with Article 1.2 of this Agreement.

12. Termination

Either NIAID or Provider may terminate this Agreement by giving written notice to the other Party at least thirty (30) days prior to the desired termination date.

13. Severability

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

14. Entire Agreement

This Agreement, together with all appendices including SRF(s), constitutes the entire agreement between the Parties and supersedes any prior or contemporaneous oral or written agreement or communications between them with respect to the subject matter thereof. For the avoidance of doubt, the terms and conditions of this NCEA replaces and supersedes those of any prior NCEA signed between the Parties.

15. Survivability

The provisions of Articles 3, 5, 6, 7, 8, 9, 13 and 15 will survive the termination or expiration of this Agreement.

16. Authorized Signatory

The individual signing this Agreement on behalf of Provider certifies that he/she is an authorized representative of Provider and has authorization to bind the Provider to the terms and conditions of this Agreement.

17. Agreement Format

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

Accepted and agreed by the Parties through their duly authorized representatives as of the date of the last authorized signatory below.

The terms and conditions of this Agreement shall, at NIAID's sole option, be considered by NIAID to be withdrawn from Provider's consideration and the terms and conditions of this Agreement, and the Agreement itself, to be null and void unless this Agreement is duly executed by Provider and a fully executed Agreement is received by NIAID within sixty (60) days from the date of NIAID's authorized signature below. Any changes to the terms and conditions of this Agreement made by Provider that is not authorized by NIAID shall have no effect.

FOR NIAID:

_____

Emily Erbelding, MD, MPH

Director

DMID/NIAID/NIH

5601 Fishers Lane Room 7G51
MSC 9826
Bethesda, MD 20892-9826
Phone: (b) (6)

Date: _____

FOR PROVIDER:

DocuSigned by:
(b) (6)
Signer Name: Mikihiko Kato
Signing Reason: I approve this document
Signing Time: 5/6/2020 | 9:47:25 AM EDT
ADEE84EB3F0041668084F91A3C304823

_____

NAME: Mikihiko Kato

TITLE: President

ORGANIZATION: FUJIFILM Pharmaceuticals U.S.A., Inc.

ADDRESS: 200 Summit Lake Dr.
Valhalla, NY 10595

PHONE: 617-301-0811

EMAIL: (b) (6)

Date: 5/6/2020

DMID Administrative POC:

Kimya B. Alexander, MS

Health Specialist

DMID/NIAID/NIH

5601 Fishers Lane Room 7F29
MSC 9826

Bethesda, MD 20892-9826
Phone: (b) (6)

Email: (b) (6)

PROVIDER Scientific POC:

NAME: Robert P. Lenk, Ph.D.

TITLE: Virologist/Pharmaceutical Development

ORGANIZATION: FUJIFILM Pharmaceuticals U.S.A., Inc.

ADDRESS: 200 Summit Lake Dr.
Valhalla, NY 10595

PHONE: 713-444-2986

EMAIL: (b) (6)

DO NOT COMPLETE
DMID NCEA – Appendix <# >, Service Request Form (SRF)

To be completed by NIAID.

NCEA Tracking Number:	
NCEA Effective Date:	
Task Order/CPO:	
Test Site(s):	
Estimated Cost:	

If applicable, please fill in information.

Active NIH Grant Y/N?	
Grant Number:	
Grant Start Date:	
Grant End Date:	

Provider - please fill in requested contact information.

Date SRF submitted (m*m/dd/yy*):	
Provider Scientist:	*Last:* *First:*
Institution:	
Street Address:	
City/State/Zip:	
Country:	
Phone:	
Other Phone:	
Email:	

Please answer the following questions.

Has the Product/Compound been previously evaluated through NIAID's contract testing laboratories or contract coordinating facilities? If yes and the ARB# is known, please include.	☐ Yes ☐ No ☐ Not Sure
Did the Provider's Institution develop this Product/Compound?	☐ Yes ☐ No
If not how was it obtained by the Institution?	

"Confidential Information submitted and attached to this Service Request Form (SRF) shall remain confidential for five (5) years from the date of last signature on the SRF. This SRF and the Services(s) to be performed hereunder are subject to all the terms and conditions of the NIAID Non-Clinical Evaluation Agreement executed between Provider and NIAID."

For Provider:	For NIAID:
Signature:	Signature:
_____	_____
Name:	Name:
Title:	Title:
Institution:	Institution:
Date: (mm/dd/yyyy) _____	Date: (mm/dd/yyyy) _____

Product/Compound Description
Product/Compound Name(s):

Brief Description of Product/Compound (include info on purity, sterility, and potency, 100 word limit):

Brief Description of Relevant Product/Compound History (100 word limit):

Product Classification:

☐ Small Molecule
☐ Well Characterized Biological (CDER regulated)
☐ Vaccine or Other Biologic (CBER regulated)
☐ Challenge Material
☐ Other

Biosafety Level:

Classification of Services Requested:

☐ Animal Models
☐ Therapeutic Manufacturing Services
☐ Vaccine Manufacturing Services
☐ In Vitro Assessments for Antimicrobial Activity: Bacteria, Fungi, Viruses, Parasites, Vectors, and Toxins

Provider Supplied Materials:
Brief Description of the material(s) and/or information that will be provided (100 word limit):

Delete this sentence and the following information, and replace with a brief description of the Materials and/or Information that will be provided.

Preclinical Services Requested
Brief Description of Requested Service(s) (100 word limit):

Delete this sentence and the following information, and replace with a brief description of the type(s) of Preclinical Services evaluation work to be performed. As appropriate, specify whether the evaluation will be in vitro or in vivo, pathogen(s) including isolate/strain, animal model(s), the material and/or information that will submitted for evaluation.