

FLOW-DOWN CLAUSES FOR REGENERON'S OTHER TRANSACTION AGREEMENT WITH THE BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

The provisions of this Attachment relate to Regeneron Pharmaceuticals, Inc.'s ("Regeneron") Other Transaction Agreement(s) (the "OTA" or "Prime Contract") with the Biomedical Advanced Research and Development Authority ("BARDA"). The provisions of this Attachment are hereby incorporated into the agreement to which this Attachment relates (the "Subcontract" and, the party to such agreement (other than Regeneron), "Subcontractor").

I. Site Visits and Project Meetings.

- A. Subcontractor shall provide the U.S. Government and Regeneron with reasonable access to sites and facilities at which work under this Subcontract is conducted. At Regeneron's reasonable request, Subcontractor will participate in meetings with the U.S. Government and Regeneron. Meetings may occur in Washington, D.C. or other locations.
- B. With advance notice to Subcontractor in writing from the U.S. Government or Regeneron, the U.S. Government or Regeneron may place a person-in-plant at any Subcontractor laboratory or manufacturing site involved in performing this Subcontract.

II. Access to Records. The Comptroller General, at its discretion, shall have access to and the right to examine records of any entity that participates in performance of this Subcontract or any lower-tier agreement regardless of tier, to the extent related to such performance, for a period of three (3) years after final payment is made under this Subcontract or a lower-tier agreement, as applicable. This requirement shall not apply with respect to any entity that participates in the performance of this Subcontract or a lower-tier agreement that has not entered into any other agreement (contract, grant, cooperative agreement, or other transaction) that provides for audit access by a U.S. Government entity in the year prior to the date of this Subcontract or any lower-tier agreement, as applicable. This Paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law.

III. Data Rights.

A. Allocation of Principal Rights.

- 1. For data, which is defined to include computer software and source code, that is produced under the Subcontract to the extent developed with U.S. Government funds, Subcontractor grants to the U.S. Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such data to exercise government purpose rights, as defined in 48 C.F.R. § 252.227-7013(a)(13), except as expressly provided elsewhere in this Subcontract. For data produced under this Subcontract, excluding computer software, to the extent developed with private funds,

Contains Confidential Commercial or Financial Information

Subcontractor grants to the U.S. Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such data to exercise limited rights as defined in 48 C.F.R. § 252.227-7013(a)(14) and, if applicable, limited by the OTA. The U.S. Government will not obtain any rights in computer software or source code produced under this Subcontract to the extent developed with private funds.

2. Subcontractor agrees to retain and maintain in good condition all data produced under this Subcontract and necessary to achieve practical application, as defined in 48 C.F.R. § 27.301, of any invention conceived or first actually reduced to practice by Subcontractor under this Subcontract as limited by the terms of the Prime Contract (a “Subject Invention”) in accordance with the Subcontractor’s established record retention practices. In the event of an exercise of the U.S. Government’s compulsory licensing rights as set forth under this Section III, Subcontractor agrees, upon written request from the U.S. Government, to deliver at no additional cost to the U.S. Government, all existing data produced under this Subcontract necessary to achieve practical application, as defined in 48 C.F.R. § 27.301, of the relevant invention within sixty (60) calendar days from the date of the written request.
- B. Marking of Data. The Subcontractor will mark any data delivered under this Subcontract subject to limited rights, as defined in 48 C.F.R. § 252.227-7013(a)(14), with appropriate markings.
- C. Lower Tier Agreements. Subcontractor shall ensure that its affiliate and lower-tier agreements regardless of tier, for experimental, developmental, or research work entered into after the effective date of this Subcontract, and submitted for reimbursement under this Subcontract, are consistent with this Section III. Within 90 calendar days of the execution of this Subcontract, Subcontractor shall execute modifications to existing third-party agreements to ensure compliance with terms and conditions outlined herein.
- D. Identification and Disposition of Data. Subcontractor shall keep copies of all data relevant to the Subcontract as required by the Food and Drug Administration (“FDA”) for the time specified by the FDA. In addition, Subcontractor shall provide regulatory data to Regeneron. Subcontractor shall permit the U.S. Government to review any other data determined by the U.S. Government to be relevant to the Subcontract.
- E. Publication and Publicity. No data or other information obtained under this Subcontract shall be released or publicized without at least thirty (30) calendar days’ notice to Regeneron. The U.S. Government’s support shall be acknowledged in all such publications substantially as follows: “This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under a

subcontract to OT number: HHSO100201700020C (or such other contract number provided by Regeneron).” Subcontractor shall, in good faith, comply with the instructions of the U.S. Government (including instructions provided by Regeneron on behalf of the U.S. Government) concerning any such publication (or content thereof) identified by the U.S. Government as containing sensitive (e.g., national security) information.

IV. Patent Rights.

- A. Allocation of Principal Rights. Unless Subcontractor shall have notified the U.S. Government (in accordance with Subparagraph (B) below) that Subcontractor does not intend to retain title, in which case title shall vest with the U.S. Government, Subcontractor shall retain the entire right, title, and interest throughout the world to each Subject Invention developed under the Subcontract, consistent with the provisions of the Subcontract. With respect to any Subject Invention developed under the Subcontract, in which Subcontractor retains title, the U.S. Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. For clarity, this license does not include the right to use or allow others to use the Subject Invention for commercial purposes.
- B. Invention Disclosure, Election of Title, and Filing of Patent Application.
1. Subcontractor shall disclose in writing each Subject Invention to the BARDA Other Transaction Agreement Technical Representative (“OTTR”) within 12 months after the inventor discloses it in writing to Subcontractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and the Subcontract under which the Subject Invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the Subject Invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the Subject Invention, or whether a manuscript describing the Subject Invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Subcontractor shall promptly notify the OTTR of the acceptance of any manuscript describing the Subject Invention for publication and any on sale or public use.
 2. Subcontractor shall elect in writing whether or not to retain ownership of any Subject Invention by notifying the OTTR within 2 years of disclosure to the agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 calendar days prior to the end of the statutory period.

3. Subcontractor shall file either a provisional or a non-provisional patent application for an elected Subject Invention within 1 year after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, Subcontractor shall file the application prior to the end of that statutory period. If Subcontractor files a provisional application, it shall file a non-provisional application within 12 months of the filing of the provisional application.
 4. Subcontractor may request that the U.S. Government extend the time for disclosure, election, or filing under subparagraphs (B)(1), (B)(2) and (B)(3) of this Section IV.
 5. If Subcontractor determines that it does not intend to retain title to any such Subject Invention, Subcontractor shall notify the U.S. Government, in writing, within two (2) years of disclosure to the U.S. Government. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the U.S. Government to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.
- C. Conditions When the U.S. Government May Obtain Title. Upon the U.S. Government's written request, Subcontractor shall convey title to any Subject Invention to the U.S. Government if Subcontractor fails to disclose or elects not to retain title to the Subject Invention within the times specified in this Section IV; provided, that the U.S. Government may only request title within sixty (60) calendar days after learning of the failure of Subcontractor to disclose or elect within the specified times.
- D. Rights to Subcontractor and Protection of Subcontractor Right to File.
1. Subcontractor shall retain a fully paid up, sub-licensable, nonexclusive, royalty-free license throughout the world in each Subject Invention to which the U.S. Government obtains title. Subcontractor's license extends to Subcontractor's subsidiaries and other affiliates, if any, within the corporate structure of which Subcontractor is a party and includes the right to grant licenses of the same scope to the extent that Subcontractor was legally obligated or permitted to do so at the time this Subcontract was executed. The license is otherwise transferable only with the approval of the U.S. Government, except when transferred to an affiliate or successor of that part of Subcontractor's business to which the Subject Invention pertains. The U.S. Government approval for license transfer shall be provided on a timely basis (and in no event later than 90 calendar days following Subcontractor's request) and shall not be unreasonably withheld.

2. Subcontractor's license may be revoked or modified by the U.S. Government to the extent necessary to achieve expeditious practical application of the Subject Invention pursuant to an application for an exclusive or nonexclusive license submitted consistent with appropriate provisions at 37 C.F.R. Part 404. Subcontractor's license shall not be revoked in that field of use or the geographical areas in which Subcontractor has achieved practical application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.
3. Before revocation or modification of Subcontractor's license, the U.S. Government shall furnish Subcontractor with a written notice of its intention to revoke or modify the license, which notice shall include a detailed explanation of the reasons for such revocation or modification, and Subcontractor shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

E. Action to Protect the U.S. Government's Interest.

1. Subcontractor agrees to execute or to have executed and promptly deliver to the U.S. Government all instruments necessary to (i) establish or confirm the rights the U.S. Government has throughout the world in those Subject Inventions to which Subcontractor elects to retain title, and (ii) convey title to the U.S. Government when requested under this Section IV and to enable the U.S. Government to obtain patent protection throughout the world in that Subject Invention.
2. Subcontractor agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by Subcontractor, each Subject Invention made under the Subcontract so Subcontractor can comply with the disclosure provisions of this Section IV. Subcontractor shall use reasonable efforts to instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.
3. Subcontractor shall notify the U.S. Government of any decisions not to continue the prosecution of a patent application for a Subject Invention, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent of a Subject Invention, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

4. Subcontractor shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: “This invention was made with Government support under a subcontract to Agreement HHSO100201700020C (or such other contract number provided by Regeneron), awarded by the U.S. Department of Health and Human Services. The Government has certain rights in the invention.”
- F. Lower Tier Agreements. Subcontractor shall ensure that its affiliate and lower-tier subcontracts regardless of tier, for experimental, developmental, or research work entered into after the effective date of this Subcontract and submitted for reimbursement under this Subcontract, contain invention reporting and assignment requirements sufficient to permit Subcontractor to comply with this Section IV. Within 90 days of the execution of this Subcontract, Subcontractor shall execute modifications to the existing third party agreements to ensure compliance to terms and conditions outlined herein.
- G. Reporting on Utilization of Subject Inventions. Subcontractor agrees to submit to the U.S. Government, during the term of this Subcontract, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Subcontractor or its licensees or assignees. Subcontractor also agrees to provide additional reports as may be requested by the U.S. Government in connection with any march-in proceedings undertaken by the U.S. Government regarding compulsory licensing rights.
- H. Compulsory Licensing Rights.
1. Subcontractor agrees that, with respect to any Subject Invention in which it has retained title, the U.S. Government has the right to require Subcontractor, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Subcontractor, assignee, or exclusive licensee refuses such a request, the U.S. Government has the right to grant such a license within the field itself only if the U.S. Government determines that:
 - a) Action is necessary to alleviate the following health or safety needs that may affect the United States and Subcontractor (itself or through its assignee, subcontractor or licensee) is unwilling or unable to manufacture or supply the Subject Invention to address such needs:
 - (1) Declaration for Public Health Emergency by the Secretary of HHS;
 - (2) Determination that there is a significant potential for a public health emergency that has a significant potential to

effect the national or health security of U.S. citizens as determined by the Secretary of Health and Human Services; or

- (3) Declaration by World Health Organization Director General of a public health emergency of international concern.

V. Foreign Access to Technology.

1. During the term of this Subcontract and for five (5) years thereafter, Subcontractor agrees to comply with all applicable laws regarding export controls and not to export any technology, including without limitation discoveries, innovations, know-how, and inventions, to any U.S. embargoed countries. Subcontractor shall provide timely notice to the U.S. Government and Regeneron of any proposed transfers from the Subcontractor of technology developed under this Subcontract to non-U.S. firms or institutions, including any firms or institutions that are owned or substantially controlled by non-U.S. citizens, permanent residents, or governments. If the U.S. Government determines that a transfer may have adverse consequences to the national security interests of the United States, then Regeneron, Subcontractor, its vendors, and the U.S. Government shall jointly endeavor to find alternatives to the proposed transfer that obviate or mitigate potential adverse consequences of the transfer.
2. In any event, Subcontractor shall provide written notice to BARDA and Regeneron of any proposed transfer described in paragraph (1) above at least thirty (30) calendar days prior to the proposed date of transfer. Such notice shall cite this Section V and shall state specifically what is to be transferred and the general terms of the transfer. No transfer shall take place until a decision is rendered.
3. Subcontractor shall ensure that its lower tier agreements regardless of tier for experimental, developmental, or research work entered into after the Effective Date and submitted for reimbursement under the Subcontract are consistent with this Section V.

VI. Cost Reimbursement.

- A. This Section VI is applicable only to the extent the Subcontract contemplates payment on a cost-reimbursement, time-and-materials, or labor-hours basis.
- B. Costs shall be accounted for using Generally Accepted Accounting Principles. Any costs for which Subcontractor seeks reimbursement must be reasonable, allocable to the Subcontract, and allowable under 48 C.F.R. Part 31.

1. To be reasonable, a cost must be (1) generally recognized as an ordinary or necessary part of the business; (2) follow sound business practices; (3) acceptable to a prudent business person; (4) compliant with applicable laws; and (5) consistent with Subcontractor's established practices.
 2. Costs of travel must comply with the Federal Travel Regulations, 41 C.F.R. §§ 301-04, unless otherwise approved by Regeneron.
- C. Subcontractor's initial indirect rates will not be subject to adjustment unless approved by Regeneron and the U.S. Government.
- VII. Prohibition on a ByteDance Covered Application. In accordance with Section 102 of Division R of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328), the No TikTok on Government Devices Act, and its implementing guidance under Office of Management and Budget (OMB) Memorandum M-23-13, dated February 27, 2023, "No TikTok on Government Devices" Implementation Guidance, in the performance of the Services, Subcontractor shall not use the social networking service TikTok (or any successor application or service developed or provided by ByteDance Limited or an entity owned by ByteDance Limited) in any equipment (or interconnected system or subsystem of equipment) that is (i) required to be used under this Agreement or that is otherwise used to a significant extent in the performance of the Services and (ii) used in the automatic acquisition, storage, analysis, evaluation, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information. The equipment referred to in the preceding sentence includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources. This prohibition applies to equipment used or provided by the Subcontractor under this Agreement, including equipment provided by the Subcontractor's employees, but does not include any equipment acquired by Subcontractor that is incidental to this Agreement. Subcontractor shall insert the substance of this clause in all subcontracts under this Agreement, including subcontracts for the acquisition of commercial products or commercial services.
- VIII. Prohibition on Subcontractor Involvement with Terrorist Organizations. Subcontractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism.
- IX. Termination for Convenience.
- A. To the extent the U.S. Government terminates the Prime Contract, Regeneron may terminate this Subcontract to that same extent upon written notice to Subcontractor.

- B. Regeneron will work in good faith to obtain U.S. Government reimbursement for costs incurred by Subcontractor under this Subcontract prior to the notice of termination.

X. General Terms

- A. Subcontractor shall not acquire any property for the performance of this Subcontract with a value greater than \$50,000 without the prior written approval of Regeneron.
- B. Subcontractor's performance shall be consistent with Title VI of the Civil Rights Act of 1964 relating to non-discrimination in federally assisted programs.
- C. Subcontractor shall not perform work involving animal or human substances or subjects without Regeneron's express written approval. If performing such activities, Subcontractor agrees to abide by all applicable rules and good laboratory practices governing such research, including, but not limited to, 45 C.F.R. Part 46, the Animal Welfare Act, regulations of the Department of Agriculture, the National Institutes of Health Policy Manual 3044-2 on the protection of personnel who work with nonhuman primates, and the Public Health Service Policy on Humane Care of Use of Laboratory Animals.
- D. Subcontractor shall comply with any applicable Good Manufacturing Practice regulations, such as 21 C.F.R. §§ 210, 211, 600.
- E. Subcontractor understands that the Subcontract is subject to U.S. Government approval and that information disclosed to Regeneron under this Subcontract may be disclosed to the U.S. Government.
- F. To the extent the Subcontract involves the use of toxins, biological agents, or select agents, Subcontractor shall ensure it is in compliance with applicable laws, including but not limited to 42 C.F.R. Part 73, and that it has registered with the requisite U.S. Government agencies.
- G. In performing this Subcontract, Subcontractor will comply with any applicable anti-bribery and anti-corruption laws of the territory in which work under this Subcontract takes place.
- H. Unless the Subcontract is awarded on a fixed-price basis without analysis of labor costs, Subcontractor shall comply with the salary rate limitation at 48 C.F.R. § 352.231-70 (Dec 2015).