

Portfolio Company Agreement

Managing Entity (ME): Trustees of Boston University	Portfolio Company:
Managing Entity Principal Investigator (PI): Kevin Outterson	Portfolio Company Principal Investigator (PI):
Project Title:	
Agreement Period of Performance: Start Date: End Date:	Total Amount Funded: \$
Portfolio Company Agreement Number:	Cost Sharing: \$ (see Attachment 2)
<input checked="" type="checkbox"/> Subject to FFATA	
<p>On behalf of the global program known as the CARB-X Global Antibacterial Accelerator ("CARB-X"), Managing Entity hereby awards a cost-reimbursable Agreement, as described above, to Portfolio Company.</p> <p>This Agreement includes Attachments 1 (Statement of Work), 2 (Budget, Cost Share), 3A (Managing Entity Contact Information), 3B (Portfolio Company Contact Information), 4 (Reporting), and 5 (Other Funder Terms & Conditions), which are hereby incorporated.</p> <p>In signing this Agreement, Portfolio Company certifies that it agrees to the terms and conditions of the Agreement, including all Attachments. This Agreement is not final, binding or enforceable until countersigned below by Managing Entity.</p>	
By an Authorized Official of Managing Entity: Director, Special Projects, Policy and Process	By an Authorized Official of Portfolio Company: Name, Title, Date:

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Section A

Definitions

Accelerator: The global program established by the Managing Entity, also known as the CARB-X Global Antibacterial Accelerator (“CARB-X”).

Agreement: The body of this document and Attachments, including any amendments or modifications which are expressly incorporated in and made a part of this legally binding Portfolio Company Agreement between Managing Entity and Portfolio Company.

CARB-X Global Funding Partners: All entities providing direct funding for CARB-X, including the U.S. Department of Health and Human Services/Office of the Assistant Secretary for Preparedness and Response/The Biomedical Advanced Research and Development Authority (HHS/ASPR/BARDA), the Wellcome Trust, Bill and Melinda Gates Foundation, and The German Federal Ministry of Education and Research, and any future CARB-X funders (“Funders”).

This Agreement is awarded by the Managing Entity using funds from the CARB-X Global Funding Partners in combination as determined by the Managing Entity. This Agreement is funded in part by the U.S. Government as largest governmental funder of CARB-X; thus the U.S. Government has specific rights and responsibilities as described in this Agreement.

Computer Software:

1. To perform and further this Agreement:
 - (i) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and
 - (ii) Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.
2. Does not include computer databases or computer software documentation.

Data: Recorded information, regardless of form or the media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files data processing or computer programs (software), statistical records and other research data. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Direct Costs: Direct costs are those which can be identified specifically with a particular sponsored project and which can be directly assigned to such activities, relatively easily with a high degree of accuracy. For example, salaries of the individuals who will work on the project and supplies required to complete the project.

Equipment: Any tangible personal property costing \$5,000 or greater, other than property actually consumed during the execution of work under this Agreement.

Executive Level II Salary Cap: The Federal Executive Schedule Level II salary rate limitation, as detailed on the [U.S. Office of Personnel Management \(OPM\) Website](#).

Field: Any work performed that relates to or falls within the scope of the BARDA¹ Mission or as agreed to by the Joint Oversight Committee.

Global Accelerator Network: A network of antibacterial accelerator entities that will complement the capabilities of CARB-X.

Governance Board: A governing body comprised of global funding partners.

Indirect Costs: Facilities and Administrative (F&A) are costs that are not readily identifiable with individual projects. They are also referred to as overhead or indirect costs (IDC). F&A type costs include utility costs, depreciation of buildings and equipment, operations and maintenance costs, and administration such as Human Resources, Accounts Payable, and Purchasing.

Invention: Any invention or discovery that is or may be patentable or otherwise protectable under Title 35 of the United States Code.

Know-How: Information, practical knowledge, techniques, and skill development by Portfolio Company in the performance of work under this Agreement necessary for the Practical Application of a Subject Invention (as defined below) within the Field. Know-How does not include patents and patent applications.

Limited Rights: The rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the U.S. Government solely for research purposes for the Field. U.S. Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement and any operative nondisclosure agreement concerning the Data. The U.S. Government may not, without the prior written permission of Portfolio Company, release or disclose the Data outside the U.S. Government, inclusive of BARDA supported Subject Matter Expert contractors, use the Data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the Data to be used by another party. The Parties shall maintain the confidentiality of all Data subject to or designated as falling within Limited Rights.

Made: The conception or first actual reduction to practice of the invention(s) as defined in this Agreement.

Managing Entity (ME): the Trustees of Boston University.

¹ **BARDA Mission:** To foster and accelerate the development and innovation of medical countermeasures and technologies and address unmet public health needs that are directly related to medical countermeasure requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics. Specific detail of the BARDA Mission can be found in the National Health Security Strategy (2019-2022), National Biodefense Strategy (2018), and the PHEMCE Strategy and Implementation Plan (2017-2018). The BARDA Mission is subject to change as laws, regulations and authorizations change. Any statutory or regulatory updates that modify this mission are automatically incorporated into this Agreement.

Option: Additional periods of performance, entered into by bilateral agreement pursuant to a Statement of Work (SOW) and budget, by which Managing Entity may provide funding for additional activities.

Other Transaction Agreement Officer (OTAO): Responsible U.S. Government official for CARB-X's award from HHS/ASPR/BARDA, authorized to bind the U.S. Government.

Other Transaction Agreement Specialist (OTAS): Supporting official that assists and represents the OTAO.

Other Transaction Agreement Technical Representative (OTAR): Primary U.S. Government official for all technical matters related to CARB-X's award from HHS/ASPR/BARDA.

Parties: Managing Entity and the Portfolio Company.

Period of Performance: The entire term during of this Agreement, commencing with the Start Date and culminating on the End Date stated on the cover page of this Agreement or in any modifications thereof.

Portfolio Company (PC): Selected applicants working independently of Managing Entity, funded to advance development and innovation of antibacterial therapeutics, preventatives, diagnostics and related technologies.

Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or U.S. Government regulations, available to the public for a regulatory approved product.

Project: The activities carried out by the Portfolio Company in its performance of the Statement of Work (Attachment 1) under this Agreement.

Project IP Rights: All patents, know-how, and trade secret rights, in each case, to inventions that are conceived or first actually reduced to practice in the Portfolio Company's performance of the Project during the Term.

Subject Invention: Any Invention of the Portfolio Company Made in the performance of work under this Agreement in the Field.

Term: Term refers to the Agreement Period of Performance as defined above unless the Agreement is terminated by Managing Entity pursuant to Section B, Article 4, in which case the Term will commence on the first day of the Period of Performance and finish as of the date described in the Managing Entity's notice to the Portfolio Company of early termination.

Section B

General Terms and Conditions

- 1) Matters concerning the technical performance under this Agreement should be directed as follows: For Managing Entity, to the Principal Investigator and CARB-X Chief of R&D as shown in Attachment 3A. For Portfolio Company, to the Principal Investigator as shown in Attachment 3B. Technical reports are required as shown in Attachment 4.
- 2) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Agreement, and any changes requiring prior approval, should be directed as follows: Portfolio Company communications shall be directed to the CARB-X Finance & Grants Manager, as shown in Attachment 3A. Managing Entity communications shall be directed to the Administrative Contact, as shown in Attachment 3B. Unless otherwise specifically provided elsewhere in the Agreement, any modifications to this Agreement require the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.
- 3) **No-cost extensions** require the approval of Managing Entity. Any requests for a no-cost extension should be directed to Managing Entity's Administrative Contact, as shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
- 4) **Termination:**
Managing Entity may terminate this Agreement with thirty days written notice to the Portfolio Company's Administrative Contact, as shown in Attachment 3A. Notwithstanding the foregoing, if Federal Awarding Agency or a non-Federal Funder terminate Managing Entity's award, Managing Entity may terminate this Agreement in accordance with Funder's requirements. Managing Entity shall pay Portfolio Company for termination costs as allowable under the applicable cost principles as detailed in Article 7 below.
- 5) **Key Personnel:**
Portfolio Company's Principal Investigator, as identified in Attachment 3A, is considered essential to the Statement of Work to be performed under this Agreement. Substitution or substantial reduction in commitment of Portfolio Company's Principal Investigator requires the prior written approval of Managing Entity.
- 6) **Independent Entity:**
In its performance of the Statement of Work under this Agreement, Portfolio Company shall be an independent entity and not an employee or agent of Managing Entity.
- 7) **Cost Principles:**
The cost principles applicable to this Agreement are as set forth at 48 CFR Subpart 31.2, applicable to commercial organizations, 48 CFR Subpart 31.3, applicable to educational organizations, or 48 CFR Subpart 31.7, applicable to nonprofit organizations, unless otherwise specifically provided elsewhere in the Agreement.

8) **Invoices/Payment:**

a. Portfolio Company shall submit invoices on a monthly basis for allowable costs incurred. Upon receipt of proper invoices, Managing Entity shall reimburse Portfolio Company.

b. All invoices must be submitted in English. Invoices may be submitted using Portfolio Company's standard invoice, but at a minimum shall include current and cumulative costs (including cost-share) in accordance with the budgeted cost categories, along with the Agreement number, and certification (see language below). Invoices that do not reference the Agreement number shall be returned to Portfolio Company.

c. **Required Certification** on invoices: "By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Agreement. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729-3730 and 3801-3812)."

d. Invoices should be submitted to Managing Entity as directed in Attachment 4 (Reporting). Questions concerning invoice receipt or payments should be directed to the Managing Entity's Financial Contact, as shown in Attachment 3A.

e. All costs and financial information must be expressed in U.S. dollars using an exchange rate applicable at the time the invoice is submitted and including documentation of the conversion rate used. When calculating the exchange rate Managing Entity requires all non-US entities to use the currency converter, OANDA +/- 2%. All payments will be in U.S. dollars.

f. A General Ledger report of incurred expenses must be provided in support of each invoice. Additional documentation with applicable translation in English to support claimed expenses shall be provided upon request, and must remain accessible for auditing purposes. Additional requests for supporting documentation may include, but are not limited to, payroll distribution records, time sheets, time and effort reports for subject personnel, vouchers, expense reports, requisitions and receipts for non-personnel expenditures and contracts issued for services.

g. All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Portfolio Company. The Managing Entity reserves the right to reject an invoice.

h. **Final Invoice:** A final statement of cumulative costs incurred, including cost sharing, marked "FINAL," must be submitted to Managing Entity as directed in Attachment 4 (Reporting) NOT LATER THAN 45 days after the end of the period of performance. The final statement of costs shall constitute Portfolio Company's final financial report.

9) **Cost-Sharing:**

Cost-sharing under this Agreement will be achieved through direct commitments of Portfolio Company. Portfolio Company's cost-share requirement is stated on the first page of this Agreement and further detailed in the Budget (Attachment 2), and is based on a prescribed percentage of total costs. To be allowable as Portfolio Company cost-sharing, costs must comply with the cost principles as stated in Article 7 above and with any funding restrictions specified in this Agreement.

10) Funding Restrictions:

- a. Costs incurred prior to the Start Date of this Agreement are not allowable without prior approval by Managing Entity.
- b. Indirect costs are reimbursable, up to a maximum of 15% of total project direct costs. Managing Entity must approve the budget, including calculation of allowable indirect costs.
- c. Patent costs are allowable, up to a \$20,000 limit. Any amount in excess of this limit requires prior approval from the Managing Entity.
- e. All salaries (inclusive of any bonuses) paid under the Agreement (including cost-sharing) are capped at the rate of Executive Level II. See definition in Section A.
- f. Bonuses may be allowable if within the period of performance and only for the portion that does not exceed the salary cap once added to salary. Portfolio Company must have a written policy and process to support any request to include bonuses in the approved budget. Bonuses are subject to Managing Entity review and approval.
- g. Equipment: Managing Entity prior approval is required for equipment purchases over \$5,000 not included in the approved budget.
- h. Fringe Benefits: If Portfolio Company does not have federally negotiated fringe benefits rates, invoices must reflect actual fringe benefits costs.
- i. Administrative costs, including but not limited to utilities, rent, subscription, general supplies and Users licenses and fees for general business use, are not allowable for reimbursement as direct costs. These items can be recovered through the indirect cost rate approved by Managing Entity for the Portfolio Company.
- j. Travel:
 - i. For-profit Portfolio Companies: Travel shall be in accordance with Federal Travel Regulation, <https://www.ecfr.gov/current/title-41/subtitle-F>, and with the Fly America Act (49 USC 40118) and Open Skies Agreements as detailed at <http://www.gsa.gov/portal/content/103191>.
 - ii. Non-profit Portfolio Companies (including educational institutions): Travel shall be in accordance with 2 CFR 200 Subpart E, and with the Fly America Act (49 USC 40118) and Open Skies Agreements as detailed at <http://www.gsa.gov/portal/content/103191>.

11) Rebudgeting: The following require prior approval by Managing Entity. Requests should be submitted as specified in Article 2 above.

- a. Rebudgeting of any direct cost category \geq 25%.
- b. Addition of any new contracted service \geq \$50,000.
- c. Equipment not included in the original budget.
- d. PI effort reduction \geq 25%.

12) Lower-tier Research Agreements:

Portfolio Company may not issue any lower-tier research agreements under this Agreement without the prior approval of Managing Entity. This requirement for prior approval does not include contracted services. Any approved lower-tier research agreements must comply with the terms and conditions of this Agreement, as applicable to the lower-tier collaborating entity.

13) Audit/Access to Records:

a. Managing Entity, or a third party designated by Managing Entity, reserves the right to inspect, upon Managing Entity's reasonable advance notice and during normal business hours, Portfolio Company's physical facilities, all aspects of the Statement of Work undertaken under this Agreement, and all books, records, and documents of any kind pertaining to the Agreement. Portfolio Company agrees to provide copies of any records, receipts, accounts or other documentation to Managing Entity in a timely fashion as reasonably requested by Managing Entity.

b. The United States Comptroller General, at its discretion, shall have access to and the right to examine records of the Portfolio Company, for a period of three (3) years after final payment is made. This requirement only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law.

c. Portfolio Company must keep all usual and proper records and books of accounts in accordance with Generally Accepted Accounting Principles (GAAP) relating to performance of the Statement of Work for a minimum period of three (3) years after completion of closeout of the Agreement and after the final Report has been submitted to Managing Entity and approved, or until 06/30/2028, whichever is later. During this period, Managing Entity, or an authorized representative, or Funders shall have the right to audit, at its own expense, all financial books, accounts, and records of funds received, and costs and commitments incurred under this Agreement. If any audit reveals a material discrepancy or error in reporting, Portfolio Company will repay the unallowable cost(s), including any applicable indirect costs. Portfolio Company expressly acknowledges its understanding that its activities pursuant to this Agreement and all financial books, records, and accounts pertaining thereto may be subject to audit by Managing Entity, and Portfolio Company agrees to cooperate fully in the performance of any such audit.

d. Portfolio Company shall forward to Managing Entity (carbxinv@bu.edu) a copy of any company CARB-X program specific audit, and a copy of company's annual financial audit, within 30 days of completion.

14) Site Visits:

It is anticipated that site visits by Managing Entity to Portfolio Company may take place. The visits may focus on scientific, budgetary, and business capacity issues. BARDA staff or any other CARB-X Funders may attend such site visits.

15) Data Rights:

a. The Portfolio Company will retain custody of and primary rights to any data developed under this award, subject to the U.S. Government's Limited Rights of access consistent with U.S. law, including 45 CFR 75.322, and this Agreement.

b. For Data produced by Portfolio Company, to the extent produced from technology developed with U.S. Government funds, the Portfolio Company grants to the U.S. Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise Limited Rights except as expressly provided elsewhere in this Agreement. The U.S. Government will not obtain any rights in Computer Software produced under this Agreement to the extent developed exclusively with private funds.

c. Portfolio Companies must retain and maintain in good condition all Data produced under this Agreement and necessary to achieve Practical Application of any Subject Invention in accordance with the Portfolio Company's established record retention practices. Portfolio Companies agree, 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 Agreement by Portfolio Company and necessary to achieve Practical Application of the relevant Subject Invention within sixty (60) calendar days from the date of the written request, or sooner in case of an emergency as determined by BARDA.

16) Publications:

a. All planned publications and public presentations (e.g., abstracts, manuscripts, journal articles, posters, public regulatory filings, slide decks, etc.) related to this Project must be coordinated with Managing Entity. For relevant publications, Portfolio Company will provide the CARB-X Communications Team (carbxpr@bu.edu) and the CARB-X Alliance Lead with advance copies at least five (5) days before they are submitted or re-submitted for publication. For relevant presentations, Portfolio Company will provide the CARB-X Communications Team and the CARB-X Alliance Lead with a copy at least five (5) days in advance of any public presentation. Managing Entity will have no role in the preparation, editing or approval of the material. Managing Entity review will be limited to verification of references to CARB-X and required Funder acknowledgments and disclaimers. These requirements shall survive termination or expiry of this Agreement and shall continue in force for two years after the termination or expiration of this Agreement.

b. See also Section C, sub-section 5.02 "Open Science" and Attachment 5 (Other Funder Terms and Conditions)

17) Press Releases:

a. Any press release directly relating to CARB-X, or this Project will be coordinated in advance with the Managing Entity. Portfolio Company will provide the CARB-X Communications Team (carbxpr@bu.edu) and CARB-X Alliance Lead with advance copies of all press releases related to the Project at least five (5) days before release. These requirements shall survive termination or expiry of this Agreement and shall continue in force for two years after the termination or expiration of this Agreement.

b. All BARDA support shall be acknowledged in all such press releases 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; Antibacterials Branch, under Agreement number 75A50122C00028."

c. See also Attachment 5 (Other Funder Terms and Conditions).

18) Copyrights:

Portfolio Company grants to Managing Entity an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Agreement for the purpose of conducting and publishing anonymized academic research conducted by, or

performed in collaboration with, the Managing Entity Principal Investigator, and to the extent required to meet Managing Entity's obligations to the CARB-X Funders.

19) **Patent Rights:**

Contact information for any reporting to OTAR, OTAS, or OTA0 required by this Article will be provided by CARB-X. For any reports, notifications or any other submissions sent directly to OTAR, OTAS, or OTA0, copies shall be sent to the Managing Entity Administrative Contact as shown in Attachment 3A, and to cxinvent@bu.edu.

a. Allocation of Principal Rights

- i. This Agreement does not grant any express or implied rights in Portfolio Company's background intellectual property.
- ii. It is ASPR policy that the results and accomplishments of the activities that it funds should be made available to the public. Portfolio Company is expected to make the results and accomplishments of its activities available to the research community and to the public at large. If the outcomes of the research result in inventions, the provisions of the Bayh-Dole 5 Act of 1980, as implemented in 37 CFR Part 401, apply.
- iii. Portfolio Company retains the entire right, title, and interest throughout the world to each Subject Invention Made by Portfolio Company in the performance of work under this Agreement, consistent with the provisions of this Article. With respect to any such Subject Invention in which Portfolio Company 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 consistent with the provisions of this Article.

b. Invention Disclosure, Election of Title, and Filing of Patent Application

- i. Managing Entity requires that Portfolio Company disclose in writing each Subject Invention to the OTAR, within 12 months after the inventor discloses it in writing to Portfolio Company personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this Agreement 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 OTAR, the Managing Entity requires that Portfolio Company promptly notify the OTAR of the acceptance of any manuscript describing the Subject Invention for publication and any on sale or public use.
- ii. Managing Entity requires that Portfolio Company elect in writing whether or not to retain ownership of any Subject Invention by notifying the OTAR within 2 years of disclosure to the OTAR. 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 OTAR to a date that is no more than 60 calendar days prior to the end of the statutory period.
- iii. Managing Entity requires that Portfolio Company 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, the Managing Entity requires that Portfolio Company file the application prior to the end of that statutory period. If the Portfolio Company files a provisional application, it shall file a non-provisional application within 12 months of the filing of the provisional application.

iv. Portfolio Company may request from OTAR extensions of time for disclosure, election, or filing under subparagraphs (b)(i), (b)(ii) and (b)(iii) of this clause.

v. If Portfolio Company determines that it does not intend to retain title to any such Subject Invention, the Portfolio Company shall notify the OTAR, 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, and with concurrence of the Governance Board, Portfolio Company shall convey title to any Subject Invention to the U.S. Government if Portfolio Company fails to disclose or elects not to retain title to a Subject Invention; provided, that the U.S. Government may only request title within 1 year (365 calendar days) after learning of the failure of Portfolio Company to disclose or elect within the specified times.

d. Rights to Portfolio Company and Protection of Portfolio Company's Right to File

Portfolio Company retains 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. The Portfolio Company license extends to the Portfolio Company's Affiliates (outside this Agreement), if any, within the corporate structure of which a Portfolio Company is a party and includes the right to grant licenses of the same scope to the extent that Portfolio Company was legally obligated or permitted to do so at the time the Agreement 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 a Portfolio Company'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 Portfolio Company's request) and shall not be unreasonably withheld.

i. A Portfolio Company 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 CFR Part 404. A Portfolio Company's license shall not be revoked in that field of use or the geographical areas in which Portfolio Company has achieved Practical Application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.

ii. Before revocation or modification of a Portfolio Company's license, the U.S. Government shall furnish Portfolio Company 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 Portfolio Company 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 Portfolio Company's license should not be revoked or modified.

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

i. Managing Entity requires that Portfolio Company execute or 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 Portfolio Company elects to retain title, and (ii) convey title to the U.S. Government when requested and to enable the U.S. Government to obtain patent protection throughout the world in that Subject Invention.

ii. Managing Entity requires that Portfolio Company 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 Managing Entity, each Subject Invention Made by Portfolio Company in the performance of work under this Agreement so Portfolio Company can comply with the disclosure provisions of paragraph b.i of this Article. Managing Entity requires that Portfolio Company instruct its 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.

iii. Managing Entity requires that Portfolio Company notify the OTAR of any Portfolio Company 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.

iv. Managing Entity requires that Portfolio Company 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 U.S. Government support under Agreement Number 75A50122C00028, awarded by the U.S. Department of Health and Human Services. The U.S. Government has certain rights in the invention.”

f. Reporting on Utilization of Subject Inventions

i. Managing Entity requires that Portfolio Company submit, during the term of the Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Portfolio Company, Sub-Recipients, licensees, or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. Managing Entity also requires that Portfolio Company 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 in accordance with Subparagraph g of this Article. Consistent with 35 U.S.C. § 202(c)(5), the U.S. Government agrees it shall not disclose such information to persons outside the U.S. Government without permission of Portfolio Company.

ii. All required reports shall be submitted to the OTAS, OTAO, and OTAR.

g. Compulsory Licensing Rights

The Managing Entity requires Portfolio Company to agree that, with respect to any Subject Invention in which Portfolio Company has retained title, the U.S. Government has the right to require a Portfolio Company, 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 a Portfolio Company, 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:

- i. action is necessary because the Portfolio Company or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
- ii. action is necessary to alleviate health or safety needs which are not reasonably satisfied by a Portfolio Company, assignee, or their licensees;
- iii. action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by a Portfolio Company, assignee, or licensees; or
- iv. action is necessary because the agreement required by 35 U.S. Code § 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 35 U.S. Code § 204.

20) Protection of Human Subjects:

a. The Portfolio Company agrees that the rights and welfare of human subjects involved in research supported by this Agreement shall be protected in accordance with 45 CFR Part 46 and shall require that all human subjects research is conducted pursuant to a current Assurance of Compliance on file with the Office for Human Research Protections (OHRP). The Managing Entity requires Portfolio Companies to provide certification that an Institutional Review Board (or its equivalent, if the research will take place outside of the US), has reviewed and approved the research procedures, which involve human subjects, in accordance with 45 CFR Part 46 and its Assurance of Compliance.

b. The Managing Entity will obtain documentation from Portfolio Company concerning mechanisms and procedures in place to protect the safety of participants in any clinical trials funded under this Agreement, and will provide such documentation to BARDA. Approval of a clinical study protocol by both BARDA and Managing Entity is required before work under a protocol may begin.

c. The Managing Entity requires Portfolio Company to bear full responsibility for the performance of all work and services involving the use of human subjects under this Agreement and ensure that the work is conducted in a proper manner and as safely as is feasible. Nothing in this Agreement shall be deemed to constitute Managing Entity or any sub-consortium, agent or employee of the Managing Entity, including but not limited to any Portfolio Company or its contracted agents, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the U.S. Government. Managing Entity requires Portfolio Company to agree that it will discharge its obligations, duties, and undertakings and

the work pursuant thereto, whether requiring professional judgement or otherwise, as an independent organization without imputing liability on the part of the U.S. Government for the acts of the Portfolio Company or its employees.

d. If at any time during the performance of this Agreement, the OTAO or Managing Entity determines, in consultation with the OHRP, that the Portfolio Company or any performance site conducting work on behalf of the Portfolio Company is not in compliance with any of the requirements and/or standards stated in paragraphs (i) and (ii) above, OTAO or Managing Entity may immediately suspend, in whole or in part, work and further payments under this Agreement for the Portfolio Company's work until the Portfolio Company or performance site corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Portfolio Company or performance site fails to complete corrective action within the period of time designated in the OTAO's written notice of suspension, the OTAO may, in consultation with OHRP, terminate the Portfolio Company's Agreement in whole or in part, and the Portfolio Company's or performance site's name may be removed from the list of those performers with approved Federal Wide Assurances.

21) Human Subjects Restriction:

In accordance with Article 20 above, funds under this Agreement may not be expended, no obligations may be made, and individuals may not be enrolled for any research involving human subjects at any site, domestic or foreign, that does not have an Office for Human Research Protections (OHRP)-approved Assurance to comply with the requirements of 45 CFR Part 46 to protect human subjects, and an Institutional Review Board (IRB) approval of the research that satisfies the requirements of 45 CFR Part 46.

In addition, BARDA and Managing Entity approval is required for each clinical study. Managing Entity will notify Portfolio Company of approval on a study-specific basis.

Failure to comply with the above requirements may result in suspension and/or termination of this Agreement, withholding of support, audit disallowances, and/or other appropriate action.

22) Human Materials (Assurance of OHRP Compliance):

a. Managing Entity requires that the acquisition and supply of all human specimen material obtained by the Portfolio Company is in full compliance with applicable Federal, State and Local laws and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

b. The Managing Entity requires Portfolio Company to provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this Agreement, by collaborating sites, or by subcontractors under this Agreement, were obtained with prior approval by OHRP of a Federal Wide Assurance in place, and have complied with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all such collaborating sites engaged in research, without OHRP-approved Assurances, whether domestic or foreign, receiving U.S. Government funds.

c. Provision by the Portfolio Company to the Managing Entity of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310), certifying IRB review and

approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the “Protection of Human Subjects Assurance Identification/IRB Certification/ Declaration of Exemption”, Form OMB No. 0990-0263 (formerly Optional Form 310)

23) Other Research-Related Activities:

This Agreement does not include research involving human embryonic stem cell research and cloning or research on transplantation of human fetal tissue.

24) Needle Exchange:

Portfolio Company shall not use Agreement funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

25) Care of Live Vertebrate Animals:

a. The Managing Entity requires that, before undertaking animal-related activities located in the U.S. where the species is regulated by the United States Department of Agriculture (USDA), the Portfolio Company registers with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28 or conducts animal work at a research facility registered with the USDA. The Managing Entity requires the Portfolio Company to furnish evidence of the registration.

b. The Managing Entity requires Portfolio Company and research facilities in the U.S. to acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

c. The Managing Entity requires Portfolio Company to agree that the care, use, and intended use of any live vertebrate animals in the performance of this Agreement shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the performance site’s current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4), as applicable. In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this Agreement, the OTAO or Managing Entity determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Portfolio Company or performance site conducting work on behalf of any Portfolio Company are not in compliance with any of the requirements and standards stated in paragraphs (i) through (iii) above, the OTAO or Managing Entity may immediately suspend, in whole or in part, work and further payments under the Portfolio Company’s Agreement until the Portfolio Company or performance site corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Portfolio Company or performance site fails to complete corrective action within the period of time designated in the OTAO’s or Managing Entity’s written notice of suspension, the OTAO or Managing Entity may, in consultation with OLAW, NIH, terminate the Portfolio

Company's Agreement in whole or in part, and the Portfolio Company's or performance site's name may be removed from the list of those contractors with Animal Welfare Assurances.

e. Any Portfolio Company or performance site conducting research on behalf of any Portfolio Company may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. Information concerning this program may be obtained by contacting your regional office below or the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

26) Animal Welfare:

a. The Managing Entity requires that all research involving live, vertebrate animals is conducted in accordance with the [PHS Policy on Humane Care and Use of Laboratory Animals](http://grants1.nih.gov/grants/olaw/references/phspol.htm). This policy may be accessed at: <http://grants1.nih.gov/grants/olaw/references/phspol.htm>. Animal studies shall not begin until the performance site's IACUC or IACUC-equivalent reviews and provides final approval of the study protocol.

b. When a performance site is located in a foreign country, the Portfolio Company will ensure that procedures normally followed in the foreign countries to protect live vertebrate animals are expected to afford protections that are at least equivalent to those required for U.S. performance sites.

27) Information on Compliance with Animal Care Requirements:

a. Registration with the USDA is required to use regulated species of animals for biomedical purposes, as applicable. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.) in the U.S.

b. The PHS Policy is administered by OLAW, <https://olaw.nih.gov/>. An essential requirement of the PHS Policy, <https://olaw.nih.gov/policies-laws/phs-policy.htm>, is that every institution using live vertebrate animals must obtain an approved domestic or foreign assurance from OLAW before they can receive funding from any component of the U.S. Public Health Service. If a Portfolio Company does not have an assurance and will be utilizing another performance site to perform the animal work then the Portfolio Company and the performance site must have an Inter-Institutional Assurance in place to meet the HHS requirements for assurance. The request for this negotiation of this assurance must be submitted to OLAW by Managing Entity on behalf of the Portfolio Company.

c. The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals and that they comply with the regulations (9 CFR, Subchapter A) issued by the USDA under the Animal Welfare Act, as applicable. The Guide may differ from USDA regulations in some respects. Compliance with the applicable USDA regulations is an absolute requirement of this Policy, subject to the provisions of Article 26 above.

d. The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), <http://www.aaalac.org>, is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the accredited status. As of the 2015 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC accreditation is not required to conduct

biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federation of Animal Science Societies, <http://www.fass.org>.

28) Approval of Required Assurance by Law:

Subject to the provisions of Article 26, the Managing Entity requires that consistent with governing regulations, funds authorized under this Agreement may not be expended by any Portfolio Company for research involving live vertebrate animals, and that vertebrate animals are not involved in research activities by any Portfolio Company (and relevant performance sites) under this Agreement unless a satisfactory assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28 is submitted by the Portfolio Company prior to commencing research involving live vertebrate animals and approved by OLAW. Each performance site (if any) must also assure compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28, as applicable, with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at <http://grants.nih.gov/grants/olaw/olaw.htm>.

29) Animal Subjects Restriction: No research involving live vertebrate animals may begin on any Study until (1) a Memorandum of Understanding has been executed by Managing Entity, the Portfolio Company, and, if applicable, any separate Performance Site, or Portfolio Company's Contractor; (2) the Performance Site (Portfolio Company or any separate Performance Site) has an OLAW-approved assurance; (3) as applicable, there is an OLAW-approved Interinstitutional Assurance (IIA) that covers the Study; (4) the Performance Site has final approval for the Study from an IACUC or comparable animal welfare oversight body; (5) the Performance Site has made the congruency certification for the Study and (6) if applicable, satisfactory completion of the NC3R review process, and any other requirements of Section C, section 5.03, for studies involving cats, dogs, equidae (horses) and non-human primates.

30) Manufacturing Standards:

The Managing Entity requires Portfolio Company to comply with cGMP guidelines (21 CFR Parts 210-211, 600) for manufacturing, processing and packing of drugs, chemicals, biological, and reagents. The Managing Entity requires Portfolio Company to advise the HHS OTAO and OTAR immediately of any relocation of their prime manufacturing facility or the relocation of any performance site's facility. Managing Entity requires Portfolio Company to advise the HHS OTAO's and Contracting Officer's Representative immediately if at any time during the life of the contract, the items under this contract fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

31) Warranties, Limitations, Indemnification and Insurance:

a. Disclaimer of Warranties

All advice, services, work product, data or other consulting or guidance that may be provided to Portfolio Company by CARB-X, Managing Entity, any subcontractor, supplier, distributor, vendor,

or firm who executes activity in support of the Managing Entity, including those comprising the Managing Entity's Global Accelerator Network ("Managing Entity Sub-Recipients"), or any employee or agent of those entities ("Services") are and shall be provided "AS-IS", with absolutely no warranty or guarantee of any kind, either express or implied. Any and all such warranties, including the warranties of merchantability or fitness for particular purpose or any other such warranty, are expressly disclaimed. Portfolio Company expressly and irrevocably releases Managing Entity, CARB-X and Managing Entity Sub-Recipients and their employees and agents from any and all claims, liability and damages of any kind arising from the Services or Portfolio Company's use of any Services, and Portfolio Company agrees to indemnify and defend Managing Entity, CARB-X and Managing Entity Sub-Recipient and its employees and students from any and all claims, liability and damages relating to use of Services.

b. Limitations

Managing Entity, CARB-X and Managing Entity Sub-Recipients shall not be liable to Portfolio Company for any consequential, punitive, special or incidental damages, claims for lost profits, re-procurement costs, or other indirect damages, regardless of the form of action, whether in contract or in tort, including negligence, or otherwise and whether or not the Managing Entity, CARB-X or Managing Entity Sub-Recipient was advised of the possibility or likelihood of such damages.

c. Indemnification

Portfolio Company will defend and indemnify and hold Managing Entity, CARB-X, Managing Entity Sub-Recipients and Funders and their affiliates, employees, faculty members, students, trustees and agents ("Indemnified Parties") harmless from and against any demands, claims, actions, suits, losses, damages (including property damage, bodily injury and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys' fees and expenses) (collectively "Claims") arising out of or relating to Portfolio Company's and its subgrantees', subcontractors', contingent workers', employees' agents' or affiliates' performance of this Agreement, including but not limited to work involving clinical trials, trials involving human subjects, post-approval studies, field trials involving genetically modified organisms, experimental medicine, or the provision of medical/health services; breach or alleged breach of any warranty, misrepresentation or material omission made to obtain funding or Services, or any other negligent or wrongful act or omission of Portfolio Company and its subgrantees, subcontractors, contingent workers, employees, agents and affiliates ("Indemnified Activities"). Portfolio Company agrees that any activities by the Managing Entity or Funders in connection with the Portfolio Company Statement of Work, such as its review or proposal of suggested modifications to the Portfolio Company Statement of Work, will not modify or waive the Managing Entity's or Funder's rights under this paragraph. An Indemnified Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim. Portfolio Company's indemnification obligations are limited to the extent permitted or precluded under applicable federal, state or local laws, including federal or state tort claims acts, the Federal Anti-Deficiency Act, state governmental immunity acts, or state constitutions. Nothing in this Agreement will constitute an express or implied waiver of Portfolio Company's governmental and sovereign immunities, if any.

d. Insurance:

Portfolio Company will maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the Portfolio Company Statement of Work in accordance with generally-accepted industry standards and as required by law. Portfolio Company will ensure that its subgrantees and subcontractors maintain insurance coverage consistent with this section.

32) Governing Language:

In the event that a translation of this Agreement is prepared and signed by the parties, this English language version shall be the official version and shall govern if there is a conflict between this English language version and the translation. All disputes under this Agreement shall be resolved and conducted, regardless of the means or authority, in the English language.

33) Governing Law:

The validity, interpretation, performance and enforcement of this Agreement, and all rights and obligations of the parties will be governed and construed in accordance with the internal laws of the Commonwealth of Massachusetts, without regard to its rules concerning conflicts of laws.

34) Dispute Resolution:

a. This clause applicable to domestic Portfolio Companies only:

Any action, suit or other proceeding pursuant to, arising under, or concerning this Agreement or the transactions contemplated hereby will be brought exclusively in any court of competent jurisdiction in Suffolk County, Commonwealth of Massachusetts. The parties agree to take any and all necessary or appropriate action to submit to the exclusive jurisdiction of any such court.

b. This clause applicable to foreign Portfolio Companies only:

Any action, suit or other proceeding pursuant to, arising under, or concerning this Agreement or the transactions contemplated hereby will be brought exclusively in a final and binding arbitration with JAMS Boston Mediation, Arbitration and ADR Services (“JAMS”) in a venue located in Boston, Massachusetts and in accordance with the most recent JAMS Comprehensive Rules & Procedures.

35) Financial Conflicts of Interest:

This Agreement is subject to PHS-Specific Requirements Promoting Objectivity in Research (42 CFR Part 50 Subpart F). 42 CFR Part 50. 604 requires that institutions conducting PHS-funded research maintain an up-to-date, written, enforced policy on financial conflicts of interest.

Under this Agreement, the financial conflicts of interest policy of Managing Entity Portfolio Company will apply. If applying its own financial conflicts of interest policy, by execution of this Agreement, Portfolio Company certifies that its policy complies with 42 CFR Part 50.

Portfolio Company shall report any financial conflict of interest to Managing Entity’s Administrative Contact, as shown on Attachment 3A. Any financial conflicts of interest identified may subsequently be reported to Funders, before expenditure of funds authorized in this Agreement and within 45 days of any subsequently identified financial conflict of interest.

36) Export Control:

It is understood that Managing Entity is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities,

and that its obligations hereunder are contingent on compliance with applicable U.S. export laws and regulations (including the International Traffic in Arms Regulations (ITAR) and Export Administration Regulations (EAR) in activities under this Agreement. In the event that Portfolio Company intends to provide any technical information, computer software, laboratory prototypes, or other items controlled under the applicable U.S. export control laws, the Portfolio Company shall first notify Managing Entity of its intent to provide such export-controlled items or information and shall not transfer the export-controlled items or information until Managing Entity's Authorized Representative agrees in writing to accept. Prior to the transfer of any export-controlled items or information (excluding items or information designated as EAR99 under the EAR), recipient shall conspicuously designate such items or information as "Export Controlled" and identify the applicable export control category under the United States Munitions List (ITAR) or ECCN under the Commerce Control List (EAR). The transfer of any such items may require a license or authorization from the cognizant agency of the United States Government, and/or may require written assurances by the receiving party that it shall not re-export such items to certain foreign destinations and/or to certain recipients without prior approval of the cognizant government agency, and/or may require the involved individuals and entities comply with certain conditions. Managing Entity cannot guarantee that such licenses will be granted.

37) Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712):

Portfolio Company is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

38) Trafficking in Persons:

a. In accordance with Section 106 (g) of the Trafficking Victims Protection Act (TVPA) of 2000, as amended (22 U.S.C. 7104), located at 2 CFR Part 175, and implemented in accordance with OMB Interim Final Guidance, Federal Register Volume 72, No. 218, November 13, 2007, Portfolio Company, Portfolio Company's employees, and subcontractors may not:

- i. Engage in severe forms of trafficking in persons during the period of time that the Agreement is in effect;
- ii. Procure a commercial sex act during the period of time that the Agreement is in effect; or
- iii. Use forced labor in the performance of the Agreement or subcontracts under the Agreement.

b. Any violation of this term will result in termination of the Agreement.

39) Prohibition on Involvement with Terrorist Activities:

The Portfolio Company 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. It is the legal responsibility of the Portfolio Company to ensure compliance with these Executive Orders and Laws. The Portfolio Company shall ensure that its Affiliate agreements and Lower-tier Research Agreements, for experimental, developmental, or research work entered into after the Effective

Date and submitted for reimbursement under this Agreement, are consistent with this subparagraph.

40) **Reporting Matters Involving Fraud, Waste, and Abuse:**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in ASPR funded programs should report such matters to the U.S. Government Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The mailing address is:
Office of Inspector General
Department of Health and Human Services
ATTN: OIG HOTLINE OPERATIONS P.O. Box 23489
Washington, D.C. 20026

41) **Research Misconduct:**

This Agreement is subject to the research misconduct requirements as specified at 42 CFR Part 93.

42) **Lobbying:**

Portfolio Company and all employees supported with funds from this Agreement must comply with the Lobbying and political activity costs regulations in 48 CFR Subpart 31.2, 48 CFR Subpart 31.3, or 48 CFR Subpart 31.7, as applicable.

43) **Anti-Bribery and Anti-Corruption:**

Each Party agrees to perform its obligations under this Agreement in accordance with the applicable anti-bribery and anti-corruption laws of the territory in which such Party conducts business with the other Party as set forth herein. Each Party shall be entitled to exercise its termination right, under and in accordance with the terms of this Agreement, to terminate this Agreement immediately on written notice to the other Party, if the other Party fails to perform its material obligations in accordance with this article.

44) **Procurement Standards:**

Sub-Recipient is subject to the requirements set forth at 45 CFR Part 75.326 – 75.335 (Procurement Standards).

45) **Entire Agreement:**

Unless otherwise specifically provided, this Agreement and its Attachments embodies the entire understanding between the Parties, and any prior or contemporaneous representations, either oral or written, are superseded.

Section C

CARB-X Special Terms and Conditions

Article I: The Project

Section 1.01

The Portfolio Company has applied for funding from CARB-X in support of activities originally set forth during the application process, and as negotiated and formalized in the Statement of Work in Attachment 1 (the "Statement of Work"). The obligations of this Agreement pertain only to the activities in the Statement of Work, which are to be led by the Principal Investigator named in Attachment 3B, and which constitute the Portfolio Company's conduct of research and development ("R&D") to reduce the threat to human health from drug-resistant infections (the "Project"). The Portfolio Company shall furnish or arrange for the provision of all the necessary services, qualified personnel, material, equipment, and facilities as needed to perform the Project to completion.

Section 1.02 The Project consists of a Period of Performance which may be extended by amendment to include one or more further work segments.

Section 1.03 Work performed during the initial Period of Performance and during each successive work segment constitute independent, non-severable, discrete work segments that cannot be subdivided for separate performance and are each necessary for the Project. The Project shall contain multiple R&D activities that, when reviewed in total, shall result in a defined end product.

Section 1.04 Managing Entity and the Company Support Team ("CST") provided by CARB-X will evaluate whether individual Milestones have been met on an on-going basis. If an individual Milestone is not met by the agreed date (and where this is not the subject of an immediate review as set out at Article II), Managing Entity may either:

- (a) amend the Milestone in agreement with the Portfolio Company, provided that:
 - (i) either (A) the Company Support Team together with the Post-Award Advisory Board Chair or (B) the Post-Award Advisory Board, advises that this is appropriate; and
 - (ii) the amended Milestone still delivers the agreed objectives of the current work segment;or
- (b) cease funding activities under the Agreement, in accordance with termination provisions identified in Section B, Article 4.

Section 1.05 Deliverables

- (a) The Budget and Milestones for this Agreement are described in Attachment A (Statement of Work) and Attachment B (Budget).
- (b) This Agreement requires the Portfolio Company to provide Managing Entity certain information and reports regarding the Project, including those described in Attachments 1 and 4 and Section C ("Deliverables").
- (c) Managing Entity is providing the Portfolio Company with funding, as well as business and technical support services as agreed between the Parties, for the Project. The Portfolio Company's success in completing the required Project tasks under the Period of Performance must be demonstrated to the satisfaction of Managing Entity through completion of the Statement of Work and Deliverables.
- (d) This Statement of Work in Attachment 1 may be extended, modified or terminated only as provided for in this Agreement.

Article II: Project Advancement

Section 2.01 No Automatic Advancement

- (a) Unless an amendment to the Agreement is executed by the Parties as described herein, the Project consists only of the Period of Performance. Any additional work segment must be incorporated by amendment to the Agreement.
- (b) An additional work segment may be limited by the Managing Entity, at its discretion, to conform to the time period or funding commitments of a Funder. An amendment to the Agreement shall further require and be subject to each of the other requirements in this Section.
- (c) Managing Entity will evaluate whether or not Milestones and Deliverables have been achieved to Managing Entity's satisfaction at the completion of the Period of Performance or by mutual agreement.
- (d) Managing Entity has no obligation to approve additional work segments and has no obligation to reimburse the Portfolio Company for any work unless incorporated into this Agreement.
- (e) Notice of intent to add an additional work segment shall be provided in the following manner:
 - (i) Managing Entity will give the Portfolio Company written notice through the CARB-X Post-Award Advisory Board process for the Portfolio Company's Project that a prospective work segment is being reviewed, subject to Section 2.01(c);
 - (ii) Managing Entity will endeavor to give the Portfolio Company written notice of the Managing Entity's intent to support an additional work segment within thirty (30) days following the Post-Award Advisory Board meeting for the Portfolio Company's Project; and
 - (iii) After such notice of intent to support an additional work segment is given, Managing Entity will engage in negotiations with the Portfolio Company to come to agreement on a new Statement of Work and budget to be incorporated into an amendment to the Agreement.

Article III: Monitoring

Section 3.01 The Portfolio Company's progress in furtherance of Milestones and Deliverables will be monitored as follows:

- (a) In quarterly programmatic and monthly financial reports provided by the Portfolio Company to Managing Entity as detailed in Attachment 4 (Reporting Requirements);
- (b) In the course of regularly scheduled meetings (at least once per quarter) with the Company Support Team;
- (c) By the Portfolio Company's Scientific Advisory Board (the "SAB");
- (d) By the Portfolio Company's ad hoc reports reasonably requested by Managing Entity or as detailed in Attachment 4; and
- (e) By a written Portfolio Company report provided to Managing Entity when the Portfolio Company determines it has completed a Milestone, in consultation with the Company Support Team.

Section 3.02 Portfolio Company SAB and Company Support Team

- (a) The Portfolio Company shall establish (or shall demonstrate that it has already established) an SAB within sixty (60) days of executing the Agreement and the SAB shall continue to meet regularly during the Term. The Portfolio Company will inform Managing Entity of SAB membership, including changes to SAB membership, by reporting such SAB membership to the Company Support Team.
- (b) The Company Support Team may include representatives from CARB-X and its funders.

Article IV: Portfolio Company Representations and Warranties

Section 4.01 The Portfolio Company makes the following representations and warranties:

- (a) The Portfolio Company has all requisite power and authority to execute, deliver, and perform this Agreement and to deliver the Project.
- (b) The Portfolio Company has obtained or will obtain all third-party approvals and consents required for the Portfolio Company to execute, deliver, and perform this Agreement where failure to obtain such approvals and consents would have a material adverse effect on the Portfolio Company's ability to perform its obligations under the Agreement.
- (c) The execution and performance of this Agreement by the Portfolio Company does not and will not violate or conflict with, as applicable, the Portfolio Company's charter documents, contract(s) or intellectual property agreements to which the Portfolio Company is a party, which violation or conflict would have a material adverse effect on the Portfolio Company's ability to perform its obligations under the Agreement.
- (d) The Portfolio Company will perform the Agreement and the Project in compliance with all applicable laws.
- (e) All written statements made by the Portfolio Company to Managing Entity during the application process, Presentations to the CARB-X Advisory Board, written responses to the CARB-X Due Diligence Form, Deliverables, and all other communications relating to this Agreement, are true and correct when made.
- (f) For each representation and warranty above, the statements are made: (a) as of the date of this Agreement; and (b) as of the date of any other written statement or verbal communication, when made to Managing Entity.

Article V: Stewardship and Access plus Additional Obligations

Section 5.01 Access, Not Excess

- (a) The purpose of CARB-X is to protect humanity from the most serious threats from drug-resistant bacterial infections by accelerating antibacterial product development. Over the long term, the new products invented or developed with CARB-X funding (the "Products") must be sustainably managed and used to promote "Access, Not Excess," including:
 - (i) Thoughtful and effective stewardship of new Products whose utility is diminished by resistance, to prevent inappropriate use and therefore premature resistance, in line with the [Global Action Plan on Antimicrobial Resistance](#) developed by the World Health Organization;
 - (ii) Through planning for and ensuring appropriate access to new Products, especially in low- and middle-income countries; and
 - (iii) Avoidance of misaligned commercial incentives, which go against the above-stated goals.
- (b) Therefore, the Portfolio Company agrees that Products will be manufactured, marketed, and sold under practices consistent with the applicable principles of the Davos Declaration on Antimicrobial Resistance – January 2016 or the [Industry Roadmap for Progress on Combatting Antimicrobial Resistance – September 2016](#).
- (c) The **Stewardship and Access Plan**. When its Product enters Phase III trials (or Phase IIb trials, if they are intended as the pivotal trials to support registration, or otherwise, when the Portfolio Company is preparing a Product that is not a therapeutic or preventative for First Approval as defined in Section 5.01(d) below), the Portfolio Company shall create and provide to Managing Entity within ninety (90) days, a plan reasonably describing how it intends to meet the above stewardship and access obligations for the Product, (the "Stewardship and Access Plan"). The Stewardship and Access Plan shall not include confidential business information and shall

include:

- (i) Strategy to support access and stewardship (e.g., proposed reliable production with sufficient capacity, supply systems, the broad approach to product labelling, and the broad approach to ensure economic barriers to access are as low as reasonably possible);
 - (ii) Identifying obstacles and constraints to access and stewardship;
 - (iii) Exploitation strategy for Project IP Rights, including whether it is planned for the Project IP Rights to be transferred to a third party;
 - (iv) Strategy to ensure marketing approvals are received for key territories in a timely manner; and
 - (v) Strategy for monitoring effectiveness of access and stewardship, including proposed metrics to measure success.
- (d) The Portfolio Company shall update the Stewardship and Access Plan and provide it to Managing Entity when the Product is first approved by any of the FDA, EMA (or national authorities), MHRA, or Japan's PMDA (the "First Approval"). After First Approval, the Stewardship and Access Plan shall be updated if there are significant market or product changes, or if events so require. The Portfolio Company shall use best reasonable efforts to comply with its Plan at all times.
- (e) The Stewardship and Access Plan will be a non-confidential document and the Stewardship and Access Plan held on file after First Approval will be publicly posted on the CARB-X website.
- (f) Obligations Follow the Product
- (i) If control of the Portfolio Company's Project IP Rights resulting from the Project changes, whether through sale, transfer, license, assignment or otherwise, the Portfolio Company will require the obligations of Sections 5.01, 5.03 and 6.04 to follow the Product and be incorporated into any such sale, transfer, license, assignment or otherwise to the new company (the "Acquirer"). Prompt notice will be provided by the Portfolio Company to Managing Entity of any such event. If the Acquirer accepts obligations under Sections 5.01, 5.03 and 6.04, the Portfolio Company is discharged from further obligations from Sections 5.01, 5.03 and 6.04.
 - (ii) If the Portfolio Company fails to provide the Stewardship and Access Plan as provided in Section 5.01, within ninety (90) days, Managing Entity can demand the same in writing within sixty (60) days).
 - (iii) The obligations of this Section 5.01 survive the termination or expiry of this Portfolio Company Agreement and shall continue in force until the expiration of the last patent or exclusivity periods in the United States, the European Union, The United Kingdom or Japan for any Project IP Rights (the "Project IP Expiration").
- (g) If Managing Entity informs the Portfolio Company that it is no longer receiving CARB-X funding and no longer operates CARB-X, then Wellcome Trust will assume the rights reserved to Managing Entity in this Section 5.01, and, for purposes of this Section 5.01, the Wellcome Trust is an intended third-party beneficiary of this Agreement, and is entitled to enforce its rights as described in this Section 5.01 as if it were a party hereto.

Section 5.02 Open Science

- (a) CARB-X supports the unrestricted access to the published research resulting from the Project and the public dissemination of the results or datasets underpinning any clinical trial or other preclinical or animal-based research, including positive and negative results.
- (b) Therefore, the Portfolio Company will endeavor to the greatest extent possible, consistent with timely filing of patent applications, to publish results from the Project (whether positive or negative and as described in (a) above), so that the results of this Project are placed in the peer-reviewed literature as soon as practical.

- (c) The Portfolio Company will make available any publications of research funded by CARB-X through PubMed Central (PMC) and Europe PMC (in accordance with the Wellcome Trust's Open Access policy: <https://wellcome.org/grant-funding/guidance/open-access-guidance/open-access-policy>).
- (d) The Portfolio Company will provide Managing Entity with advance copies of all publications and public presentations (e.g., abstracts, manuscripts, journal articles, posters and public regulatory findings, slide decks, etc.) involving CARB-X or the Project. For relevant publications, Portfolio Company will provide the CARB-X Communications Team (carbxpr@bu.edu) and the CARB-X Alliance Lead with advance copies at least five (5) days before they are submitted or re-submitted for publication. For relevant presentations, Portfolio Company will provide the CARB-X Communications Team and the CARB-X Alliance Lead with a copy at least five (5) days in advance of any public presentation. Managing Entity will have no role in the preparation, editing or approval of the manuscript; Managing Entity review will be limited to approval of the CARB-X messaging. An unpublished patent application will not be deemed to be a publication for the purposes of this subsection (d).

Section 5.03 Research and Development Standards and Development Diligence

- (a) The Portfolio Company shall comply with all of the following standards at all times during the Project:
 - (i) The requirements specified in Section B, Articles 20-23 and 25-29 (describing minimum U.S. Government mandated standards for research with animals and humans);
 - (ii) Where the Portfolio Company is undertaking research using non-human primates, cats, dogs or horses, the Portfolio Company must also comply with the NC3Rs review guidelines;
 - (iii) Where the Portfolio Company is undertaking research involving human participants, the Portfolio Company is required to have the relevant regulatory and ethical approvals and appropriate governance mechanisms in place before such research begins. It is the responsibility of the Portfolio Company (not Managing Entity) to ensure these approvals are received and that appropriate compensation arrangements (including insurance or indemnity cover, where available) are in place to cover research participants or their dependents against injuries or damage caused as a result of their participation in research, in accordance with local law and best practices. Managing Entity will not fund the costs of such insurance or indemnity cover, and will not be liable for any such compensation; and
 - (iv) Where a healthcare intervention is being examined as part of research, the standard of healthcare provided to a control group member must be at least equivalent to the best local, currently available and affordable standard of care. The Portfolio Company's research protocol shall include proposals for any necessary post-research health monitoring related to a volunteer's participation.
- (b) Development Diligence. Portfolio Company will use commercially reasonable efforts to develop and seek regulatory approval for at least one Product in at least one indication by the FDA, EMA (or national authorities), MHRA or Japan's PMDA. If the Wellcome Trust considers, based on scientific evidence and data, that any Project IP Rights remain not further developed by the Portfolio Company, its assignee or its licensee after the five (5) years following the end of the Term, then the Portfolio Company, its assignee or its exclusive licensee shall, with respect to such Project IP Rights, be subject to the Access Rights under Section 6.05. If Portfolio Company is engaged in scientific and technical development leading towards regulatory approval for at least one Product in at least one indication by the FDA, EMA (or national authorities), MHRA or Japan's PMDA, then Wellcome Trust shall not deem the Project IP Rights to remain not further developed. For purposes of this Section 5.03, the Wellcome Trust is an intended third-party beneficiary of this Agreement and is entitled to enforce the Access Rights as described in this

Section 5.03 as if it were a party hereto. Section 5.03 shall survive termination or expiry of the Agreement and shall continue in force for a period of 10 years.

Article VI: Intellectual Property

Section 6.01 Portfolio Company Use of the CARB-X Logo

- (a) For the limited purposes of the Portfolio Company's participation in CARB-X relating to the Project, the Portfolio Company shall be permitted to use the following logo (the "Logo") for the period of the Term (or for a longer period, if agreed between the Parties), subject to the Portfolio Company's full performance of the terms and conditions of the Portfolio Company Agreement and PROVIDED THAT the Portfolio Company shall cease to use the Logo where the conditions set out at subsections (i) and (ii) below apply:



- i) Managing Entity determines, in its sole discretion, that use of the Logo is either no longer accurate or appropriate, in any way misrepresents the Portfolio Company's participation, or for any reason reflects negatively on Managing Entity or Managing Entity's other partners, collaborators, sponsors or grantees; or
 - ii) Managing Entity, Funders, or NIAID request that the use of the Logo is discontinued.
- (b) Any other use of the CARB-X name, its Logo, service marks or trademarks, or any of its other distinguishable marks, whether registered or not, shall be limited to those granted by the express, written permission of Managing Entity. Those to whom such permission is granted must agree that Managing Entity shall remain the final arbiter of the use of the mark or Logo.

Section 6.02 CARB-X Use of Portfolio Company Logo

- (a) The Portfolio Company hereby grants Managing Entity and the institutions represented on the CARB-X Governing Board permission and the right to use the Portfolio Company's corporate logo (and other artwork as agreed to by the Parties), for presentations, CARB-X internal and external websites, and other reasonable promotional and reporting uses relating to the Project during the Term (or for a longer period, if agreed between the Parties).

Section 6.03 Project IP Rights

- (a) In addition to the reporting requirements detailed in Attachment 4 and this Section C of the Agreement, the Portfolio Company shall provide written notice to Managing Entity of any material:
 - (i) prosecution, defense or enforcement activities including any litigation or threatened litigation that is likely to have a significant impact on any Project IP Rights; and
 - (ii) completed transactions between the Portfolio Company and third parties to sublicense, transfer, or otherwise exploit the Project IP Rights.
- (b) The Portfolio Company shall use its best commercial efforts to include provisions in its contracts with its subcontractors performing service(s) requiring the subcontractors to assign to the Portfolio Company all Project IP Rights.

Section 6.04 Project IP Rights and Strategy

All rights are subject in all cases to the provisions of Section B, Articles 15, 18 and 19, applicable Federal laws and regulations governing patents and inventions, including government-wide regulations at 37 CFR part 401 and, in particular, and without limitation, to U.S. Government march-in rights set forth in 37 CFR Sect. 401.6 and 401.14 (j) (collectively, the “U.S. Government Bayh-Dole Rights”). Applicable U.S. laws and regulations are not superseded or limited by any additional special terms or conditions imposed on the Portfolio Company regarding IP. The process set out in this Section is intended to design and implement a credible IP strategy that enables the development and deployment of the Product in a manner consistent with the Wellcome Trust’s equitable access principles.

- (a) The Commercialization Plan for Targeted Territories.
 - (i) No later than six (6) months after the First Approval, unless otherwise agreed by the Parties, the Portfolio Company will describe in a confidential commercialization plan (the “Commercialization Plan”) the key countries where it intends to market the Product (the “Targeted Territories”). The list of Targeted Territories shall not be inconsistent with the Portfolio Company’s most recent Stewardship and Access Plan and will be updated by the Portfolio Company from time to time based on actual developments. The Commercialization Plan should be reasonably detailed as appropriate for a marketed Product.
 - (ii) For the Targeted Territories, particularly for high-income countries with National Action Plans on Antimicrobial Resistance, the Wellcome Trust will not exercise its Access Rights in such Targeted Territories for so long as the Portfolio Company markets the Product in such Territory or is taking steps towards marketing the product in such Territory as set forth in the Commercialization Plan and the Stewardship and Access Plan.
- (b) Negotiation of Voluntary Mechanisms for Other Territories.
 - (i) For countries that are not Targeted Territories (the “Other Territories”), the Portfolio Company and the Wellcome Trust will explore mechanisms to achieve stewardship and access objectives. This process will begin with a joint business plan addressing the Other Territories. This business plan will lay out reasonable goals and mechanisms for making the Product available in such Other Territories consistent with access and stewardship objectives. While informed by the Wellcome Trust’s overall stewardship and access objectives, this negotiation process will set the metrics and goals in the Other Territories that are acceptable to both Wellcome Trust and the Portfolio Company.
 - (ii) This business plan should include a mechanism for the Wellcome Trust (or the Wellcome Trust’s nominee) to access all intellectual property required to commercialize the Product in the Other Territories, including Project IP Rights and background intellectual property (including intellectual property which may block the exploitation of Project IP rights).
 - (iii) The Portfolio Company and the Wellcome Trust may consider the following potential mechanisms for accessing intellectual property rights referenced in Section 6.04(b)(ii):
 - 1) A voluntary sublicensing agreement process between the Portfolio Company and the Wellcome Trust (or the Wellcome Trust’s nominee);
 - 2) A Portfolio Company supply arrangement between the Portfolio Company and the Wellcome Trust (or the Wellcome Trust’s nominee) to ensure the Product is made available to ensure access is provided to the Wellcome Trust, or another party specified by the Wellcome Trust, with a specified number of doses at an agreed upon cost for distribution solely in the Other Territories;

- 3) Creation of a joint venture between the Portfolio Company and the Wellcome Trust (or the Wellcome Trust's nominee) to promote access to the Product within an appropriate stewardship framework;
 - 4) The voluntary transfer by the Portfolio Company to the Wellcome Trust (or its nominee) of intellectual property rights necessary for the Wellcome Trust to develop and exploit the Product in the Other Territories, consistent with its access and stewardship objectives; and
 - 5) Payment of a reasonable royalty by the Wellcome Trust for background intellectual property.
- (iv) In all cases, care will be taken in the business plan to prevent Product distributed in the Other Territories from being sold without the Portfolio Company's authorization in the Targeted Territories. Techniques could include distinct packaging, branding and other differentiating characteristics.
- (c) Access Rights. Should the Wellcome Trust and the Portfolio Company with respect to any Other Territory attempt but fail to agree on a mechanism and business plan as described in Section 6.04(b) by the third anniversary of the First Approval, then the Portfolio Company shall, with respect to Project IP Rights, be subject to Access Rights for the sole purpose of making the Product available in such Other Territory.
- (d) For purposes of this Section 6.04, the Wellcome Trust is an intended third-party beneficiary of this Agreement and is entitled to enforce the Access Rights as described in this section 6.04 as if it were a party hereto.
- (e) Section 6.04 shall survive termination or expiry of this Agreement and shall continue in force until the Project IP Expiration.

Section 6.05 Access Rights

- (a) The Portfolio Company agrees that with respect to any Project IP Rights in which it has acquired title, the Wellcome Trust has the right in accordance with the procedures in Subsection (b) below, to require the Portfolio Company, an assignee or exclusive licensee of Project IP Rights to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms and in timescales that are reasonable under the circumstances, for the sole purpose of making the Product available in Other Territories if Access Rights are exercised pursuant to Section 6.04(c), or for further development in the field of infectious diseases if Access Rights are exercised pursuant to 5.03(b). The exercise of Access Rights shall be predicated on the Wellcome Trust's determination that:
- (i) Such action is necessary because the Portfolio Company, licensee or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve Practical Application of the Project IP Rights in such field of use;
 - (ii) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the Portfolio Company, assignee or their licensees; or
 - (iii) Such action is necessary to meet requirements for the Wellcome Trust's charitable purpose and such requirements are not reasonably satisfied by the Portfolio Company, assignee or licensees.
- (b) Exercise of Access Rights.
- (i) The following procedures shall govern the exercise of Access Rights.
 - (ii) Whenever the Wellcome Trust receives information that it believes might warrant the exercise of Access Rights, before initiating any proceeding to exercise Access Rights, it shall notify the Portfolio Company, its assignee or exclusive licensee, as applicable, in writing of the information and request informal written or oral comments from the Portfolio Company, its assignee or exclusive licensee as well as information relevant to the matter.

In the absence of any comments from the Portfolio Company within 30 days, the Wellcome Trust may, at its discretion, proceed with the procedures below. If a comment is received within 30 days, or later if the Wellcome Trust has not initiated the procedures below, then the Wellcome Trust shall, within 60 days after it receives the comment, either initiate the procedures below or notify the Portfolio Company, its assignee or exclusive licensee, in writing, that it will not pursue Access Rights based on the available information.

- (iii) A proceeding to exercise Access Rights shall be initiated by the issuance of a written notice by the Wellcome Trust to the Portfolio Company and its assignee or exclusive licensee, as applicable and if known to the Wellcome Trust, stating that the Wellcome Trust is considering the exercise of Access Rights. The notice shall state the reasons for the proposed exercise of Access Rights in terms sufficient to put the Portfolio Company on notice of the facts upon which the action would be based and shall specify the field or fields of use in which the Wellcome Trust is considering requiring licensing. The notice shall advise the Portfolio Company, its assignee or exclusive licensee of its rights, as set forth in this section. The determination to exercise Access Rights shall be made by the Director of the Wellcome Trust or designee.
- (iv) Within 30 days after the receipt of the written notice of Wellcome Trust's intent to exercise Access Rights, the Portfolio Company, its assignee or exclusive licensee may submit in person, in writing, or through a representative, information or argument in opposition to the proposed exercise of Access Rights, including any additional specific information which raises a genuine dispute over the material facts upon which the exercise of Access Rights is based. If the information presented raises a genuine dispute over the material facts, the Director of the Wellcome Trust shall undertake or refer the matter to the Director's designee for fact-finding.
- (v) Fact-finding shall be conducted in accordance with the procedures established by the Wellcome Trust. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the Portfolio Company, its assignee or exclusive licensee the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the Wellcome Trust may present. A transcribed record shall be made and shall be available at cost to the Portfolio Company, its assignee or exclusive licensee upon request. The requirement for a transcribed record may be waived by mutual agreement of the Portfolio Company, its assignee or exclusive licensee and the Wellcome Trust. Any portion of the proceeding, including a fact-finding hearing that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the Portfolio Company, its assignee, or licensees shall be closed to the public, including potential licensees. The Wellcome Trust shall not disclose any such information obtained during an Access Rights proceeding to persons outside the Wellcome Trust and CARB-X (including CARB-X Funders) except when such release is authorized by the Portfolio Company, its assignee or exclusive licensee.
- (vi) The person conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the Director of the Wellcome Trust or designee promptly after the conclusion of the fact-finding proceeding along with a recommended determination. A copy of the findings of fact shall be sent to the Portfolio Company, its assignee or exclusive licensee by registered or certified mail. The Portfolio Company, its assignee or exclusive licensee and the Wellcome Trust representatives will be given 30 days to submit written arguments to the Director of the Wellcome Trust or designee; and, upon request by

the Portfolio Company, its assignee or exclusive licensee, oral arguments will be held before the Director of the Wellcome Trust or designee that will make the final determination.

- (vii) In cases in which fact-finding has been conducted, the Director of the Wellcome Trust or designee shall base his or her determination on the facts found, together with any other information and written or oral arguments submitted by the Portfolio Company, its assignee or exclusive licensee and the Wellcome Trust representatives, and any other information in the record. The consistency of the exercise of Access Rights with the objectives of promoting the utilization and public availability of inventions arising from funded research and protecting the public against nonuse or unreasonable use of inventions shall also be considered. In cases referred for fact-finding, the Director of the Wellcome Trust or designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. Written notice of the determination whether Access Rights will be exercised shall be made by the Director of the Wellcome Trust or designee and sent to the Portfolio Company, its assignee or exclusive licensee by certified or registered mail within 90 days after the completion of fact-finding or 90 days after oral arguments, whichever is later, or the proceedings will be deemed to have been terminated and thereafter no Access Rights based on the facts and reasons upon which the proceeding was initiated may be exercised.
 - (viii) The Wellcome Trust may, at any time, terminate a proceeding if it is satisfied that it does not wish to exercise Access Rights.
 - (ix) Any Portfolio Company, assignee or exclusive licensee adversely affected by Wellcome Trust's final determination to exercise Access Rights under this Section 6.05 may, at any time within 60 days after the determination is issued, seek independent review of such determination by filing a civil action in the Courts of England and Wales. For the purposes of such action, the governing law of England and Wales shall apply. The scope and standard of review of the Wellcome Trust's determination in such actions shall be that which would apply to U.S. Government determinations under Bayh-Dole Act petitions to the United States Court of Federal Claims (as allowed for in 35 U.S. C. §203(b)). In cases described in subsections (i) and (iii) of Section 6.05(a) above, a determination by the Director or designee unfavorable to the Portfolio Company (or its assignee or exclusive licensee) shall be held in abeyance pending the completion of any such independent review.
- (c) Interpretive Guide. The Access Rights described herein are patterned on and intended to be similar in scope and effect as the U.S. Government Bayh-Dole Rights, as effective on the date this Agreement has been signed.

Article VII: Budget

Section 7.01

- (a) At the end of the Period of Performance, or prior to any amendment authorizing an additional work segment, the Portfolio Company and the Managing Entity will perform a budget reconciliation to determine:
 - (i) Whether the Portfolio Company fully met its cost share obligation.
 - (ii) If the Portfolio Company did not meet its cost share obligation in full, the Managing Entity may withhold payment or demand a refund to recover the unmet cost share obligation.
 - (iii) In the event the Portfolio Company exceeds its cost share obligation, the Managing Entity will not reimburse any amounts above the cost share obligation.

Attachment 1

Statement of Work

Attachment 2

Budget, Cost Share

Attachment 3A

Managing Entity Contact Information

Managing Entity:	Trustees of Boston University	
Address:	881 Commonwealth Avenue Boston, MA 02215-1300	
Managing Entity Principal Investigator:	Kevin Outterson, Professor, Boston University	
Address:	771e Commonwealth Avenue Boston, MA 02215-1401	
Telephone:617-358-8653		E-Mail: mko@bu.edu
Managing Entity Administrative Contact:	Pamela A. Murphy	
Address:	Sponsored Programs 25 Buick Street Boston, MA 02215-1301	
Telephone: 617-353-4060		E-Mail: palmurph@bu.edu
Managing Entity Financial Contact:	Elaine Eakes	
Address:	Sponsored Programs 25 Buick Street Boston, MA 02215-1301	
Telephone: 617-358-5118		E-Mail: eeakes@bu.edu
CARB-X Chief of Research & Development:	Erin Duffy	
Address:	771e Commonwealth Avenue Boston, MA 02215-1401	
Telephone: 617-353-1295		E-Mail: emduffy@bu.edu
CARB-X Finance & Grants Manager:		
Address:	771e Commonwealth Avenue Boston, MA 02215-1401	
Telephone:		E-Mail:
CARB-X Alliance Lead:		
Address:	771e Commonwealth Avenue Boston, MA 02215-1401	
Telephone:		E-Mail:

CARB-X Research Compliance Manager: Heather C. Tobin	
Address: 771e Commonwealth Avenue Boston, MA 02215-1401	
Telephone: 617-358-3743	E-Mail: hctobin@bu.edu
Managing Entity Authorized Official: Various	
Address: Sponsored Programs 25 Buick Street Boston, MA 02215-1300	
Telephone: 617-353-4365	E-Mail: subaward@bu.edu

Attachment 3B

Portfolio Company Contact Information

Attachment 4

Reporting Requirements

All reports shall be in English. All information provided to CARB-X under this Agreement may be shared with Managing Entity Funders as well as members of the CARB-X Governance Board for non-proprietary purposes relating to oversight under this Agreement.

Routine Reporting Requirements

The section below includes routine (frequent) reporting requirements. All reports should be submitted as stated.

Quarterly progress reports will be submitted to Managing Entity through Box as specified by the CARB-X Alliance Lead (see Attachment 3A), on a date that will be determined in advance with the CST. Reports should include programmatic components as detailed in Attachments 1 and 2. Quarterly progress reports are not required for the period when the final report is due.

Monthly invoices and financial projections: Invoices will be submitted through Salesforce within 5 business days of the close of monthly books. Invoice requirements are subject to modification via written notice to the Portfolio Company from the Managing Entity. Financial projections will be updated via Salesforce as applicable and should include direct cost and cost-share components for actual and projected expenditures and explanations of budget variances from the approved budget as requested.

Company Support Team Meetings: For all formal CST Meetings, to be held at a frequency determined in advance by the CST, Portfolio Company will submit: (1) an agenda for each meeting at least 5 business days in advance of meeting; and (2) meeting minutes within 5 business days after each such meeting. Final agendas and minutes will be saved in Box by Portfolio Company.

Invention Reports: See Section B, Article 19 for requirements related to invention reporting.

Clinical Reporting Requirements

The section below includes Clinical reporting requirements if applicable. All reports should be submitted to the CARB-X Chief of R&D, CARB-X Alliance Lead, and CARB-X Research Compliance Lead (see attachment 3A), unless indicated otherwise below.

Clinical Studies Status Updates: Portfolio Company shall provide the CARB-X Chief of Research and Development with a status update of clinical studies that are actively enrolling patients to include by study site: cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and SAEs; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal. Status update shall also include a report of all changes in the status of any ongoing clinical study protocols. Portfolio Company shall provide such status updates on a monthly basis.

Clinical Advisory Board (CAB) Meeting: A Clinical Advisory Board including external technical advisors will be convened by CARB-X, to provide guidance to Portfolio Companies on the clinical trial strategy and design. The one-time meeting would be targeted to take place at the start of the preclinical stage, approximately 9-months to a year ahead of filing an IND or equivalent.

CARB-X Clinical Trial Steering Committee (CTSC): Starting one month prior to clinical study startup activities and through last subject, last visit, Portfolio Company, CARB-X and BARDA will hold regular, biweekly meetings (via teleconference). Follow-up meetings may be required by CARB-X beyond last subject, last visit.

Changes in the status of ongoing clinical study protocols:

a. **Major Changes:** Portfolio Company must notify CARB-X within three (3) calendar days and provide copies of documents related to all major changes in the status of any ongoing clinical study protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both, and dates it is valid
- All changes in informed consent documents, identified by version number, dates, or both, and dates it is valid
- Termination or temporary suspension of patient accrual
- Termination or temporary suspension of the protocol
- Any change in IRB approval
- Any other problems or issues that could affect the participants in the studies.

Notification of major changes should be by email to the CARB-X Chief of R&D, Alliance Lead, and Research Compliance Lead (see attachment 3A), followed by a letter signed by Portfolio Company's authorized business official, detailing notification of the change of status to the IRB and a copy of any responses from the IRB or IEC.

Major changes are those that:

- Alter the risk to benefit assessment
- Affect the safety of the subjects
- Add new medical, social, or psychological risks
- Significantly alter the design or scientific aims of the study
- Affect a subject's willingness to continue participation in the study

b. **All Changes:** Portfolio Company must submit a monthly report of all changes in the status of any ongoing clinical study protocols.

Required Time Sensitive Notifications on FDA safety reports of serious adverse events: Under an IND or IDE, Portfolio Company must provide FDA safety reports of serious adverse events. Portfolio Company must submit copies of such FDA safety reports to the CARB-X Chief of Research and Development, as detailed below.

a. Expedited safety report of unexpected or life-threatening experience or death: A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven (7) calendar days after the IND sponsor's receipt of the information, must be submitted to CARB-X and BARDA within 24 hours of FDA notification.

- b. Expedited safety reports of serious and unexpected adverse experience: A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 calendar days after the IND sponsor's receipt of the information, must be submitted to CARB-X and BARDA within 24 hours of FDA notification.
- c. IDE reports of unanticipated adverse device effect: A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to CARB-X and BARDA within 24 hours of FDA notification.
- d. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to CARB-X and BARDA.

FDA or EMA Audits

In the event of an FDA or EMA inspection which occurs that relates to products under this Agreement, or for any other FDA or EMA inspection that has the reasonable potential to impact the performance of this Agreement, Portfolio Company shall provide CARB-X with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) (or the corresponding forms from the EMA). Portfolio Company shall provide CARB-X with copies of the plan for addressing areas of non-conformance to FDA or EMA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plan's execution and a copy of all final responses to the FDA or EMA.

- a. Portfolio Company shall notify CARB-X within 5 business days of a scheduled FDA or EMA audit or within 12 hours of an ad hoc site visit/audit if the FDA or EMA does not provide advanced notice.
- b. Portfolio Company shall provide copies of any FDA or EMA audit report received from sub-recipients that occur as a result of this agreement or for products funded hereunder within three (3) business days of receiving correspondence from the FDA or EMA.
- c. Within five (5) business days of audit report, Portfolio Company shall provide CARB-X with a plan for addressing areas of nonconformance, if any are identified.
- d. For the purposes of this Attachment, "EMA" includes all constituent national drug regulatory authorities.

Regulatory Submissions and Correspondence

- a. Draft Clinical Study Report: submit to Managing Entity at least 20 business days prior to the anticipated FDA or other regulatory authority submission date, for submission to BARDA by Managing Entity. If corrective action is recommended, Portfolio Company will use reasonable efforts to address, in writing or by corrective action, all concerns raised by BARDA prior to FDA or other regulatory authority submission.
- b. Draft Regulatory Meeting Briefing Packets: submit to Managing Entity at least 15 business days prior to anticipated submission to the regulatory authority, for submission to BARDA by Managing Entity. If corrective action is recommended, Portfolio Company will address in writing its considerations of all concerns raised by BARDA. Portfolio Company will consider revising documents to address BARDA's concerns and/or recommendations prior to submission to regulatory authorities.

- c. Final FDA or other regulatory submissions: submit to Managing Entity concurrently or no later than 2 business days after submission to FDA or other regulatory authority, for submission to BARDA by Managing Entity.
- d. Managing Entity may request that Portfolio Company provide any regulatory correspondence (FDA, EMA, etc.) for products supported under this Agreement.

Non-Routine Reports and Notifications

The section below includes non-routine (Ad hoc) reporting requirements. These reports are event driven and are due contingent upon such events occurring. All reports should be submitted to the CARB-X Chief of R&D and Alliance Lead (see Attachment 3A). Additional report recipients are as indicated below.

Incident Report

Portfolio Company shall communicate and document all critical program concerns, risks, or potential risks with CARB-X.

- a. Due within 24 hours of activity or incident or within 12 hours for a security activity or incident. Email or telephone with written follow-up.
- b. Additional updates within 24 hours of additional developments.
- c. Portfolio Company shall submit within 3 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.
- d. If corrective action is deemed necessary, Portfolio Company must address in writing, its consideration of concerns raised by CARB-X within 3 business days of receiving such concerns in writing.

Final Reports for Clinical, Non-Clinical Studies, Manufacturing Campaigns

Managing Entity may request that Portfolio Company provide Clinical, Non-Clinical Studies, Manufacturing Campaigns, and other product development final reports to Managing Entity for review and comment.

Standard Operating Procedures

Managing Entity may request that Portfolio Company shall make internal and subcontractor Standard Operating Procedures (SOPs) available for review electronically.

QA Audits and Reports

Managing Entity reserves the right to participate in QA audits at the Portfolio Company. Upon completion of the audit/site visit the Portfolio Company shall provide a report capturing the findings, results and next steps in proceeding. If action is requested of the Portfolio Company, detailed concerns for addressing areas of non-conformance to FDA or EMA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to Managing Entity. The Portfolio Company shall provide responses from the site to address these concerns and plans for corrective action execution.

Technical Documents

Managing Entity may request that Portfolio Company provide Managing Entity with reports from the following Agreement funded activities: Process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master

Production Records, Certificate of Analysis, Clinical Studies Data or Reports, Toxicology Reports or any other reasonably requested Technical Documents.

Submission of available Audits and Financial Statements:

Portfolio Company shall forward to Managing Entity (carbxin@bu.edu) a copy of any company CARB-X program specific audit, and a copy of company's annual financial audit, within 30 days of completion.

Animal Model or Other Technology Transfer Package

Managing Entity may request that Portfolio Company provide Animal Model or Other Technology Transfer Package relevant data.

Final Reporting Requirements (Closeout/Post-Award)

The section below includes Final (Closeout) reporting requirements. All Portfolio Companies will be instructed on when and how to submit final closeout documents prior to the award end date.

Final Progress Report will be submitted to the CARB-X Chief of Research and Development (see Attachment 3A) within 30 days after the end of the period of performance.

Final Invoice: A final statement of cumulative costs incurred, including cost sharing, marked "FINAL," must be submitted through Salesforce NOT LATER THAN 45 days after the end of the period of performance. The final statement of costs shall constitute Portfolio Company's final financial report.

Invention Report: The Portfolio Company will submit to cxinvent@bu.edu a final invention report, in the form prescribed by the Managing Entity, within 30 days of the end of the Period of Performance. A negative report is required.

Post-completion Reporting

Portfolio Company shall report to the Managing Entity during the 24-month period following the completion of the Agreement any significant funding, regulatory events, or major transactions involving the Project, including new equity funding, out licensing or collaboration agreements, regulatory approvals, and litigation involving the Project, as well as the Ad Hoc reporting specified above as reasonably requested by the Managing Entity. Portfolio Company shall also annually report to the Managing Entity the Portfolio Company's Stewardship and Access Plan (as defined in Section C) after the termination of the Agreement. Reports to Managing Entity are to be submitted to the CARB-X Chief of R&D, Alliance Lead, and Managing Entity Administrative Contact (see Attachment 3A).

Attachment 5

Other Funder Terms and Conditions

Bill and Melinda Gates Foundation (“Foundation”)

PUBLICATION

In addition to the requirements detailed in Section B, Article 16 and Section C, subsection 5.02, if Portfolio Company seeks publication in a peer-reviewed journal, such publication shall be under “open access” terms and conditions consistent with the Foundation’s Open Access Policy available at: www.gatesfoundation.org/How-We-Work/General-Information/Open-Access-Policy, which may be modified from time to time. Nothing in this section shall be construed as requiring publication in contravention of any applicable ethical, legal, or regulatory requirements. Portfolio Company will mark any such publication subject to this clause with the appropriate notice or attribution, including author, date and copyright (*e.g.*, © 20<> <Name>).

COMPLIANCE

If the Agreement Scope of Work involves any trial involving human subjects, Portfolio Company will adhere to current Good Clinical Practice as defined by the International Council on Harmonisation (ICH) E-6 Standards (or local regulations if more stringent) and will obtain applicable trial insurance.

PUBLICITY

As a supplement to the requirements detailed in Section B, Article 17 (Press Releases):

Foundation prior approval is required for (a) press releases or other public announcements regarding this Agreement; and (b) any other public use of the Foundation’s name or logo. Portfolio Company must submit advance copies to CARB-X Communications Team (carbopr@bu.edu) 5 days before issuance to allow time for CARB-X coordination with Foundation to obtain necessary approvals.

Portfolio Company and Portfolio Company’s subgrantees, subcontractors, contingent workers, agents, or affiliates may not state or otherwise imply to third parties that the Foundation directly funds or otherwise endorses their activities.

PROHIBITED ACTIVITIES

ANTI-TERRORISM

Portfolio Company will not use funds provided under this Agreement, directly or indirectly, in support of activities (a) prohibited by U.S. laws relating to combating terrorism; (b) with persons on the List of Specially Designated Nationals (www.treasury.gov/sdn) or entities owned or controlled by such persons; or (c) in or with countries or territories against which the U.S. maintains comprehensive sanctions (currently, Cuba, Iran, Syria, North Korea, and the Crimea Region of Ukraine), including paying or reimbursing the expenses of persons from such countries or territories, unless such activities are fully authorized by the U.S. government under applicable law and specifically approved by the Foundation in its sole discretion.

ANTI-CORRUPTION; ANTI-BRIBERY

Portfolio Company will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision relating to the Foundation or the Scope of Work, including by assisting any party to secure an improper advantage. Training and information on compliance with these requirements is available at www.learnfoundationlaw.org.

LOBBYING AND ELECTIONEERING PROHIBITION

Portfolio Company may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. Portfolio Company acknowledges that the Foundation has not earmarked its Grant Funds to support lobbying activities or to otherwise support attempts to influence legislation. Activities will be conducted consistent with the private foundation lobbying rules and exceptions under Internal Revenue Code Section 4945 and related regulations.

OTHER LOBBYING, GIFT, AND ETHICS RULES

Portfolio Company agrees to comply with any national, state, local, or other lobbying, gift, and ethics rules applicable to the Portfolio Company Agreement Scope of Work.

Federal Republic of Germany Represented by the Federal Ministry of Education and Research (“BMBF”)

Use of the Grant

The remuneration of staff is governed by the provisions that apply to the institution where the staff is employed. All salaries paid by Portfolio Company are capped at the rate of US federal [Executive Level II](#) (see Section B, Article 10).

However, if the Agreement is used to cover expenditure on staff or expenditure for general administrative purposes **and** if the total expenditure by the Portfolio Company is covered mainly with German public funding, the Portfolio Company may not pay their employees at a higher rate than is paid to comparable German federal employees. Higher remuneration than the rates of the Collective Agreement for the Public Service (TVöD) and other payments above or outside collectively agreed rates may not be given in this case.

Use of Logo

In the case of publications and public relations measures by the Portfolio Company, e.g., on the internet or at fairs or presentations, the logo of BMBF preceded by the words “SPONSORED BY THE” must be given due prominence. All use of BMBF logo must be coordinated through CARB-X in the normal course of press releases and publications (see Section B, Articles 16-17).

Termination/Repayment

In the event that BMBF terminates Managing Entity's award, in whole or in part, Managing Entity may terminate this Agreement, in whole or in part. Managing Entity will terminate this Agreement in the case of credible fraud or serious misconduct including circumstances where the Agreement has been obtained through credible fraud or serious misconduct (e.g. deliberate deception, threats or corruption or the provision of materially false, misleading or incomplete information), if the requirements for the conclusion of the Agreement subsequently no longer apply, if funds are used inappropriately, if the Agreement is no longer being used for the intended purpose, or if a condition has arisen under which the Agreement becomes invalid.

In the event of termination, in whole or in part, the relevant portion of the Agreement must be repaid. The following repayment provisions will apply to the BMBF portion of the funding. The amount to be repaid bears annual interest at five per cent above the basic interest rate set out in Section 247 of the German Civil Code (BGB).