Cost Reimbursement Research Subaward Agreement

Pass-Through Entity (PTE): Trustees of Boston University		Subrecipient:
PTE Principal Investigator (PI): Kevin Outterson		Subrecipient Principal Investigator:
PTE Federal Award No: IDSEP160030 PTE non-Federal Award No: Agreement Dated 03/29/2017,	FAIN: IDSEP160030	Federal Awarding Agency: HHS/ASPR non-Federal Sponsor: The Wellcome Trust,
Federal Award Issue Date:	CFDA No.: 93.360	CFDA Title: see Attachment 2a
Project Title:		
Subaward Period of Performance: Start: End:	Amount Funded this Action: Total: $ Federal Award: $ non-Federal Award: $	Subaward No.

☒ Subject to FFATA (Attachment 3B) ☒ Cost Sharing (Attachment 5) Is this award R&D: ☒ Yes ☐ No

Terms and Conditions

1) PTE hereby awards a cost reimbursable subaward, as described above, to Subrecipient. The statement of work and budget for this subaward are (check one) ☐ as specified in Subrecipient's proposal dated or ☒ as shown in Attachment 5. In its performance of subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.

2) PTE shall reimburse Subrecipient not more often than monthly for allowable costs. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), subaward number, and certification, as required in 2 CFR 200.415 (a). See Attachment 2/Special Terms and Conditions #21 for required certification. Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments should be directed to the appropriate party's Financial Contact, as shown in Attachment 3. All costs and financials must be expressed in U.S. dollars using an exchange rate applicable at the time the invoice is submitted and including documentation of conversion rate used. All payments will be in U.S. dollars. Documentation with applicable translation in English to support claimed expenses must be submitted with all invoices. Supporting documentation includes, but is not limited to, payroll distribution records, time sheets, time and effort reports for subject personnel, general ledger support, vouchers, expense reports, requisitions and receipts for non-personnel expenditures and contracts issued for services. All invoices and reports shall be submitted in English.

3) A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, NOT LATER THAN 45 days after subaward end date. The final statement of costs shall constitute Subrecipient's final financial report.

4) 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 Subrecipient. PTE reserves the right to reject an invoice, in accordance with 2 CFR 200.305.

5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4

6) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward Agreement, and any changes requiring prior approval, should be directed to the appropriate party's Administrative Contact, as shown in Attachments 3A and 3B. Any such changes made to this Subaward Agreement require the written approval of each party's Authorized Official, as shown in Attachments 3A and 3B.

7) Changes made to this Subaward Agreement require the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.

8) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.

9) PTE may terminate this subaward with thirty days written notice to the Subrecipient's Administrative Contact, as shown in Attachment 3B. If Federal Awarding Agency or non-Federal Sponsor terminate PTE award, PTE will terminate this subaward. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable .

10) No-cost extensions require the approval of the PTE. Any requests for a no-cost extension should be addressed to and received by the Administrative Contact, as shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.

11) The Subaward Agreement is subject to the terms and conditions of the PTE Award (Attachment 2a) and other special terms and conditions, as identified in Attachments 2 and 6, as applicable. In the event of any conflict or inconsistency, the terms and conditions of the PTE Award and provisions of applicable Federal laws or regulations shall govern and take precedence over the terms and conditions of Attachment 6.

12) By signing this Subaward Agreement, Subrecipient makes the certifications and assurances shown in Attachments 1 and 2. This Subaward Agreement is not final, binding or enforceable until countersigned below by PTE.

By an Authorized Official of PTE: Director, Special Projects, Policy and Process	By an Authorized Official of Subrecipient: Name, Title, Date:

Attachment 1
Research Subaward Agreement
Certifications and Assurances

By signing the Subaward Agreement, the Authorized Official of Subrecipient certifies, to the best of his/her knowledge and belief, that:

Certification Regarding Lobbying

1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE. The form may be found at https://www.gsa.gov/portal/forms/download/116430

3) The Subrecipient shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U. S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters

Subrecipient certifies by signing this Subaward Agreement that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency. Subrecipients that are foreign governments or governmental entities, public international organizations, or foreign-owner or -controlled (in whole or in part) entities are not subject to the debarment or suspension certification requirement or to debarment or suspension under 2 CFR 376. All other foreign organizations and international organizations are subject to these requirements.

Audit and Access to Records

Subrecipient certifies by signing this Subaward Agreement that it complies with the Uniform Administrative Requirements (2 CFR Part 200), will provide notice of the completion of required audits and any adverse findings which impact this subaward as required by parts 200.501- 200.521, and HHS implementation 45 CFR parts 75.501-75.521, and will provide access to records as required by parts 200.336, 200.337, and 200.201, and HHS implementation 45 CFR parts 75.364, 75.365, and 75.501, as applicable.

In accordance with 45 CFR §75.501, subrecipients that are commercial organizations (including for-profit hospitals) have two options regarding audits:

(1) A financial related audit (as defined in the Government Auditing Standards, GPO Stock #020-000-00-265-4) of a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one HHS program; or, if awards are received under multiple HHS programs, a financial related audit of all HHS awards in accordance with Government Auditing Standards; or

(2) An audit that meets the requirements contained in this subpart.

Commercial organizations that receive annual HHS awards totaling less than $750,000 are exempt from requirements for a non-Federal audit for that year, but records must be available for review by appropriate officials of Federal agencies.

Foreign recipients are subject to the same audit requirements as commercial organizations.

PTE (or a third party designated by PTE) reserves the right to inspect, upon PTE's reasonable advance notice and during normal business hours, Subrecipient's physical facilities, all aspects of the Statement of Work undertaken under this Subagreement, and all

books, records, and documents of any kind pertaining to the Subagreement. Subrecipient agrees to provide copies of any records, receipts, accounts or other documentation to PTE in a timely fashion as reasonably requested by PTE.

Subrecipient will 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 Subaward Agreement and after the final Report has been submitted to PTE and approved. During this period, PTE or an authorized representative 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 Subaward Agreement. If any audit reveals a material discrepancy or error in reporting, Subrecipient will repay the unallowable cost(s). Subrecipient expressly acknowledges its understanding that its activities pursuant to this Subaward Agreement and all financial books, records, and accounts pertaining thereto may be subject to audit by the Sponsor, and Subrecipient agrees to cooperate fully in the performance of any such audit.

Attachment 2
Research Subaward Agreement
Prime Award Terms and Conditions
HHS

Agency-Specific Certifications/Assurances

In addition to all applicable public policy requirement included in Part I and Part II of the HHS Grants Policy Statement, by signing this Subaward Agreement, the authorized official of Subrecipient assures compliance with the following, as applicable:

1. **Research Misconduct.** The research misconduct requirements included in "Public Policy Requirements," HHS Grants Policy Statement Revised 1/1/07, http://www.hhs.gov/grants/grants/grants-policies-regulations/, Part II-13.
2. **Animal Welfare.** U.S. Federal and home country requirements. The animal welfare requirements contained in "Public Policy Requirements," HHS Grants Policy Statement Revised 1/1/07, http://www.hhs.gov/grants/grants/grants-policies-regulations/, Part II-12, including the requirement to file a written Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW) as detailed at https://grants.nih.gov/grants/olaw/sampledoc/index htm, and PTE Award (Attachment 2a, Other Terms/Vertebrate Animals). See also Attachment 6, section 5.03.
3. **Human Subjects.** U.S. Federal and home country requirements. The human subjects requirements contained in "Public Policy Requirements," HHS Grants Policy Statement Revised 1/1/07, http://www.hhs.gov/grants/grants/grants-policies-regulations/, Part II-9), including the requirement for an assurance (Section 4.1.15.1), as detailed at http://www hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index html, and in the PTE Award (Attachment 2a), including the CARB-X Clinical Terms of Award, and Attachment A: Research and Related Project Information. See also Attachment 6, section 5.03.
4. **Research Involving Recombinant DNA and Human Gene Transfer Research.** The requirements for recombinant DNA and Human Gene Transfer Research included in "Public Policy Requirements," HHS Grants Policy Statement Rev 1/1/07, http://www hhs.gov/grants/grants/grants-policies-regulations/, Part II-15, which are under the current NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), http://osp.od.nih.gov/officebiotechnology-activities/biosafety/nih-guidelines.
5. **Inclusion of Women, Minorities and Children in Clinical Research.** The requirements contained in PTE Award (Attachment 2a, Other Terms/Inclusion of Women, Minorities and Children) and HHS Grants Policy Statement Rev 1/1/07, http://www hhs.gov/grants/grants/grants-policies-regulations/, Part I-18, I-19, Part II-9, II-10.

General terms and conditions (as of the effective date of this Subaward Agreement):

1. Conditions on activities and restrictions on expenditure of federal funds in appropriations acts are applicable to this Subaward Agreement to the extent those restrictions are pertinent, http://grants nih.gov/grants/policy/appropriations_info.htm.
2. 2 CFR 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance)*, http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl
3. 45 CFR Part 75, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (HHS Implementation of Uniform Guidance),* http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75
4. The HHS Grants Policy Statement, including addenda in effect as of the beginning date of the period of performance. See HHS website, http://www hhs.gov/grants/grants/get-ready-for-grants-management/index html, for agency-specific grant management guidance. The following is excepted from the HHS Grants Policy Statement:
    a. The right to initiate an automatic one-time extension of the end date is replaced by the need to obtain prior written approval from the PTE.
    b. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
5. Title to equipment costing $5,000 or more that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall unconditionally vest in the Subrecipient upon acquisition without further obligation to the Federal Awarding Agency subject to the conditions specified in the HHS Grants Policy Statement and 45 CFR 75.320 (a).
6. Treatment of Program Income: ☒ Additive ☐ Other (Pass-through Entity specify alternative from HHS Agreement).
7. Travel shall be in accordance with 45 CFR Part 75 Subpart E – Cost Principles and HHS Grants Policy Statement Parts II-42, II-43 (Cost Considerations, Allowable Costs and Activities), and the Fly America Act (49 USC 40118) and Open Skies Agreements as detailed at http://www.gsa.gov/portal/content/103191.

PHS-Specific Requirements Promoting Objectivity in Research Applicable to Subrecipients (42 CFR Part 50 Subpart F)

a) 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.*" Further, "*If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators*."

Subrecipient must designate herein whether the financial conflicts of interest policy of ☐ Pass-through Entity Institution, or ☐ Subrecipient Institution (check one) will apply. If applying its own financial conflicts of interest policy, by execution of this Subaward Agreement, Subrecipient Institution certifies that its policy complies with 42 CFR Part 50.

b) Subrecipient shall report any financial conflict of interest to Pass-through Entity's Administrative Representative, as designated on Attachment 3A. Any financial conflicts of interest identified shall subsequently be reported to HHS. Such report shall be made before expenditure of funds authorized in this Subaward Agreement and within 45 days of any subsequently identified financial conflict of interest.

Special terms and conditions:

1. Automatic Carry Forward: ☐ Yes ☒ No
   (If No, Carry Forward requests must be sent to Pass-through Entity's Administrative contact, as shown in Attachment 3.)

2. In accordance with 48 CFR 3.908, Enhancement of Contractor Employee Protections, Subrecipient is hereby notified that they are required to:

   a. Inform their employees working on any Federal award that they are subject to the whistleblower rights and remedies of the pilot program;
   b. Inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and
   c. Contractors and grantees will include such requirements in any agreement made with a subcontractor or subgrantee.

3. Rebudgeting:
   a. Rebudgeting of any direct cost category ≥ 10% requires PTE prior approval.
   b. Addition of any new contracted service ≥$50,000 not included in the approved budget that represents a <10% change in the direct cost category (contracted services) requires contemporaneous notification to PTE.
   c. Addition of any new contracted service ≥$50,000 not included in the approved budget that represents a ≥10% change in the direct cost category (contracted services) requires PTE prior approval per 3.a above.

4. Trafficking in Persons - Required flow-down in full text:

   a. Provisions applicable to a recipient that is a private entity.
      1. You as the recipient, your employees, subrecipients under this award, and subrecipients' employees may not –
         i. Engage in severe forms of trafficking in persons during the period of time that the award is in effect;
         ii. Procure a commercial sex act during the period of time that the award is in effect; or
         iii. Use forced labor in the performance of the award or subawards under the award.

   See Att 2a (PTE NOA), Standard Terms and Conditions for the complete clause on Trafficking in Persons.

5. Publications:
   See Att 2a/Standard Terms and Conditions for required **acknowledgment** and **disclaimer.** See also Attachment 6, "Open Science."

   Abstracts or manuscripts from any CARB-X partner involving CARB-X data must be coordinated with PTE PI at the beginning of the writing process. Subrecipient will provide the PTE with advance copies of all manuscripts related to the Project when they are submitted or re-submitted for publication. PI will have no role in the preparation, editing or approval of the manuscript.

6. Press Releases: See also Attachment 6, "Open Science." Any press release directly relating to CARB-X will be coordinated in advance with the PTE PI. Subrecipient will provide the PTE PI with advance copies of all press releases related to the Project at least five (5) days before release.

7. Funding Restrictions: All salaries paid under the Subaward Agreement (including cost-sharing) are capped at the rate of Executive Level II. Pre-award costs are not allowed. See Att 2a, Other Terms for complete list. Facilities and Administrative Costs (F&A) are unallowable for any foreign Subrecipient.

8. Copyrights
Subrecipient ☒ grants / ☐ shall grant (check one) to PTE 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 Subaward Agreement for the purpose of conducting and publishing anonymized academic research conducted by, or performed in collaboration with, the PTE Principal Investigator, and to the extent required to meet PTE's obligations to the Federal Government under its Prime Award. Per 45 CFR 75.322(b), the subrecipient may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a Federal award. HHS/ASPR reserves a royalty-free, non-exclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

9. Data Rights
Subrecipient grants to PTE the right to use data created in the performance of this Subaward Agreement for the purpose of conducting and publishing anonymized academic research conducted by, or performed in collaboration with, the PTE Principal Investigator and to the extent required to meet PTE's obligations to the Federal Government under its Prime Award. Per 45 CFR 75.322(d), the Federal Government has the right to: (1) obtain, reproduce, publish, or otherwise use the data produced under a Federal award; and (2) authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

10. Cost Principles
Subrecipient must operate the Subaward Agreement under the Federal Cost Principles set forth in the Uniform Guidance, 2 CFR 200 Subpart E – Cost Principles.

11. Intellectual Property
See Att 2a (PTE NOA), Other Terms, "Intellectual Property."

12. Lower-Tier Subawards
Subrecipient may not issue any Subawards under this Subaward Agreement without the express prior written consent of PTE. The requirement for prior approval does not include contracted services.

13. Other Research-Related Activities
This Subaward Agreement does not include research involving human embryonic stem cell research and cloning or research on transplantation of human fetal tissue.

14. CARB-X Special Terms & Conditions
See Attachment 6 for *CARB-X Special Terms and Conditions*.

15. Fringe Benefits
If Subrecipient does not have federally negotiated rate agreement including fringe benefits rates, invoices must reflect actual fringe benefits costs.

16. Disputes (this clause applicable to foreign subrecipients only)
The parties shall attempt to resolve disputes through good faith negotiations. Any dispute arising under or related to this Subaward Agreement shall be resolved to the maximum possible extent through informal dispute resolution. Unresolved issues shall be arbitrated in accordance with the International Arbitration Rules of the American Arbitration Association.

17. Governing Language
In the event that a translation of this Subaward 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 Subaward Agreement shall be resolved and conducted, regardless of the means or authority, in the English language.

18. Governing Law

This Agreement shall be governed, construed and enforced for all purposes in accordance with the laws of The Commonwealth of Massachusetts, without regard to such laws governing choice of law. Subrecipient acknowledges that PTE is subject to the laws of the United States and PTE will not be obligated to take any action that is violative of such laws.

19. Export Control
It is understood that PTE 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 Subaward Agreement. In the event that Subrecipient intends to provide any technical information, computer software, laboratory prototypes, or other items controlled under the applicable U.S. export control laws, the Subrecipient shall first notify PTE of its intent to provide such export-controlled items or information and shall not transfer the export-controlled items or information until PTE'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. PTE cannot guarantee that such licenses will be granted.

20. Anti-terrorist Compliance
Subrecipient hereby agrees that all funds, including subawards to subrecipients, will be used in compliance with all applicable United States anti-terrorist financing and asset control laws, regulations, rules and executive orders.

21. Required Certification for Invoices (see face page Article 2)
"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 Federal award. 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)."

22. Maximum Obligation
The maximum obligation of the PTE for support of this Subaward Agreement will not exceed the total authorized amount specified on the Agreement face page. This Subaward Agreement will not be modified to provide additional funds for such purposes as reimbursement for unrecovered indirect costs resulting from the establishment of final negotiated rates. Subrecipient may rebudget allowable costs in accordance with the approved Scope of Work, applicable cost principles, and the prior approval requirements as stated in this Subaward Agreement. Any exception to this would be at the sole discretion of the PTE and the Joint Oversight Committee.

23. Negotiated Rate Agreement (as applicable)
Subrecipient must forward to PTE Financial Contact, as shown in Attachment 3a, a copy of final negotiated rate agreement as soon as it is available.

24. Equipment
PTE prior approval is required for equipment purchases over $5,000 not included in the approved budget.

25. Vertebrate Animals (term included only if applicable)
No research involving live vertebrate animals may begin on any Study until (1) a Memorandum of Understanding has been executed by Boston University, the Subrecipient, and, if applicable, any separate Performance Site; (2) the Performance Site (Subrecipient 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, and (5) the Performance Site has made the congruency certification for the Study and (6) satisfactory completion of the NC3R review process, and any other requirements of Attachment 6, Section 5.03, for studies involving cats, dogs, equidae (horses) and non-human primates.

26. Human Subjects Restriction (term included only if applicable)
Under governing regulations, Federal funds administered by the Department of Health and Human Services may not be expended for research involving human subjects and individuals may not be enrolled in research 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, the PTE award includes CARB-X Clinical Terms of Award to protect the safety of participants in clinical studies funded under the PTE award (see Attachment 2a).

Funds for this Subaward are restricted: Subaward funds may not be expended and no obligations may be made for any research involving human subjects pending Prime Sponsor and PTE approval of each clinical study in accordance with the CARB-X Clinical Terms of Award. PTE will notify Subrecipient of approval and lift this restriction on a study-specific basis through Amendment to this Subaward.

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

Attachment 2a
Research Subaward Agreement
PTE Federal Award from BARDA (HHS/ASPR)

Attachment 3A
Research Subaward Agreement
Pass-Through Entity Contacts

PTE Name: Trustees of Boston University		
Address: 881 Commonwealth Avenue		
City: Boston	State: MA	Zip Code + 4: 02215-1300
Institution Type : Educational Institution	Congressional District: 07	Registration current in SAM? Yes ☒ No ☐

PTE Administrative Contact

Name: [redacted]		
Address: [redacted]		
City: Boston	State: MA	Zip Code + 4: 02215-1300
Telephone: [redacted]	Fax: [redacted]	
E-Mail: [redacted]		

PTE Principal Investigator

Name: Kevin Outterson, Professor, Boston University		
Address [redacted]		
City: Boston	State: MA	Zip Code + 4: 02215-1401
Telephone [redacted]	Fax:	
E-Mail: [redacted]		

PTE Financial Contact

Name: [redacted]		
Address: [redacted]		
City: Boston	State: MA	Zip Code + 4: 02215-1300
Telephone: [redacted]	Fax: [redacted]	
E-Mail: [redacted]		

PTE Authorized Official

Name: Various		
Address: [redacted]		
City: Boston	State: MA	Zip Code + 4: 02215-1300
Telephone: [redacted]	Fax: [redacted]	
E-Mail: [redacted]		

Attachment 3B
Research Subaward Agreement
Subrecipient Contacts

Attachment 4
Research Subaward Agreement
Reporting Requirements

☒ A **final progress report** will be submitted to the CARB-X Chief of Research and Development within 30 days after the end of the period of performance.

☒ **Quarterly progress reports** will be submitted to CARB-X through the method specified by the CARB-X Alliance Lead on a date that will be determined in advance with the CST. Reports should include programmatic components as detailed in Att 2a, PTE Prime Award Attachment B/Reporting Table, as applicable to Subrecipient. Quarterly progress reports are not required for the period when the final report is due.

☒ **Monthly invoices and quarterly financial reports** will be submitted in the manner described herein, subject to modification via written notice to the Subrecipient. Invoices will be submitted through STAR within 5 business days of the close of monthly books. Quarterly financial reports will be submitted to the CARB-X Finance & Grants Manager and should include sponsored and cost-share components for actual and projected expenditures and explanations of budget variances from the approved budget. Quarterly reports are not required for the period when the final report is due.

☒ **Company Support Team Meetings**: For all formal CST Meetings noted in Attachment 6, Article III, to be held at a frequency determined in advance by the CST, Subrecipient 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 CDR by Subrecipient.

☒ **Clinical Studies Status Updates**: Subrecipient 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 (see Attachment 4a below). Subrecipient shall provide such status updates on a monthly basis.

☒ **CARB-X Clinical Teleconferences**: Starting one month prior to clinical study startup activities and through last subject, last visit, Subrecipient, PTE and BARDA will have CARB-X Clinical Teleconferences every two weeks. If PTE and BARDA determine that longer follow-up is required, the meetings will be scheduled beyond last subject, last visit (see Att 2a, PTE Prime Award, Clinical Terms of Award).

☒ **Invention Reports**: In accordance with 37 CFR 401.14, Subrecipient agrees to notify the Federal Awarding Agency [redacted] and copy the CARB-X R&D [redacted], and PTE's Administrative Contact within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Awarding Agency specific forms to the PTE PI within 30 days of the end of the total Subaward period of performance (including any approved Option periods) for submission to the Awarding Agency. A negative report is required.

☒ **Property Inventory Reports:**
Annual Property Inventory Reports will be submitted to PTE's Administrative contact within 30 days after the end of each 12-month period.
Final Property Inventory Report is due 30 days after the total Subaward project end date (including any approved Option periods). The Subrecipient will submit property inventory reports using Tangible Property Report (SF 428).

☒ **Other Special Reporting Requirements**:
Subrecipient invoices and monthly financial reports will be submitted through the CARB-X Digital Resources system using the Status Activity Report (STAR).

See also Att 4a (Adhoc Reporting Requirements).

All reports shall be in English. All information provided to PTE under this Subaward Agreement may be shared with members of the CARB-X Joint Oversight Committee, which includes representatives from the Wellcome Trust, BARDA, NIAID, UK/DHSC and with any other non-federal sponsors as applicable (such as the Bill and Melinda Gates Foundation), for non-proprietary purposes relating to oversight under this Subaward Agreement.

Contact Information for Reports:
CARB-X Chief of Research and Development: [redacted]
PTE Administrative Contact: [redacted]

Attachment 4a
Research Subaward Agreement
Ad hoc Reporting Requirements

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 Research and Development, [redacted]. Additional report recipients are as indicated below.

1. **Changes in the status of ongoing clinical study protocols**:
   a) Major Changes: Subrecipient must notify PTE 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 CARB-X Chief of Research and Development, followed by a letter signed by Subrecipient'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: Subrecipient must submit a monthly report of all changes in the status of any ongoing clinical study protocols.

2. **Required Time Sensitive Notifications**: Under an IND or IDE, Subrecipient must provide FDA safety reports of serious adverse events. Subrecipient must submit copies of such FDA safety reports to PTE and BARDA as detailed below. Reports to PTE are to be submitted to the CARB-X Chief of Research and Development. Reports to BARDA are to be submitted to [redacted] and the clinical lead assigned by BARDA to the project team.

   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 PTE 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 PTE 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 PTE 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 PTE and BARDA.

3. **Incident Report**
   Subrecipient shall communicate and document all critical program concerns, risks, or potential risks with PTE.
   - 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.
   - Additional updates within 24 hours of additional developments.
   - Subrecipient shall submit within 3 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.
   - If corrective action is deemed necessary, Subrecipient must address in writing, its consideration of concerns raised by PTE within 3 business days of receiving such concerns in writing.

4. **FDA or EMA Audits**
   In the event of an FDA or EMA inspection which occurs that relates to products under this Subaward Agreement, or for any other FDA or EMA inspection that has the reasonable potential to impact the performance of this Subaward Agreement, Subrecipient shall provide PTE with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) (or the corresponding forms from the EMA). Subrecipient shall provide PTE 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.
   - Subrecipient shall notify PTE 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.
   - Subrecipient 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.
   - Within five (5) business days of audit report, Subrecipient shall provide PTE with a plan for addressing areas of nonconformance, if any are identified.
   - For the purposes of this Attachment 4a, "EMA" includes all constituent national drug regulatory authorities.

The section below includes PTE Initiated non-routine [Ad hoc] reporting requirements. These reports are due three (3) business days after request. All reports should be submitted to the CARB-X Chief of Research and Development, [redacted]. Additional report recipients are as indicated below.

1. **Final Reports for Clinical, Non-Clinical Studies, Manufacturing Campaigns**
   PTE may request that Subrecipient provide Clinical, Non-Clinical Studies, Manufacturing Campaigns, and other product development final reports to PTE for review and comment.

2. **Standard Operating Procedures**
   PTE may request that Subrecipient shall make internal and subcontractor Standard Operating Procedures (SOPs) available for review electronically.

3. **Regulatory Correspondence and Submissions**
   PTE may request that Subrecipient provide any regulatory correspondence (FDA, EMA, etc.) for products supported under this agreement.

4. **QA Audits and Reports**
   PTE reserves the right to participate in QA audits at the Subrecipient. Upon completion of the audit/site visit the Subrecipient shall provide a report capturing the findings, results and next steps in proceeding. If action is requested of the Subrecipient, 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 PTE. The Subrecipient shall provide responses from the site to address these concerns and plans for corrective action execution.

5. **Technical Documents**
   PTE may request that Subrecipient provide PTE 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.

6. **Animal Model or Other Technology Transfer Package**
   PTE may request that Subrecipient provide Animal Model or Other Technology Transfer Package relevant data.

7. **Post-completion Reporting**
   Subrecipient shall report to the PTE during the 24-month period following the completion of the Subaward Agreement any significant funding, regulatory events, or major transactions involving the Project, including new equity funding, outlicensing or collaboration agreements, regulatory approvals, and litigation involving the Project, as well as the Ad Hoc reporting specified above as reasonably requested by the PTE. Subrecipient shall also annually report to the PTE the Subrecipient's Stewardship and Access Plan (as defined in Attachment 6, Article V) after the termination of the Subaward Agreement. Reports to PTE are to be submitted to the CARB-X Chief of Research and Development and PTE Administrative Contact, [redacted].

Attachment 5
Research Subaward Agreement
Statement of Work, Cost Sharing, Indirects & Budget

Attachment 6
Research Subaward Agreement

Article I. The Project.

The Subrecipient has applied for funding from the PTE in support of activities originally set forth in the Long Form Application, included for reference in this Subaward Agreement as Attachment 7, and as negotiated and formalized in the Statement of Work in Attachment 5 (the "Statement of Work"). The obligations of this Subaward 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 Subrecipient's conduct of research and development ("R&D") to reduce the threat to human health from drug-resistant infections (the "Project"). The Subrecipient 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 1.01 The Project consists of an initial phase of work (the "Base Stage"), and may be extended to include one or more further stages ("Option Stage(s)"). The Project commences on the start date of the Subaward Period of Performance as set forth on the Cost Reimbursement Research Subaward Agreement (face page) and ends in accordance with the Term as defined in this Attachment 6.

Section 1.02 Work performed during the Base Stage and during each exercised Option Stage each constitute independent, non-severable, discrete work segments that cannot be subdivided for separate performance and are each necessary for the Project. Each non-severable work segment constitutes a discrete requirement, which shall contain multiple R&D activities that, when reviewed in total, shall result in a defined end product.

Section 1.03 The PTE 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 under the end of Stage process set out at Article II), the PTE may either:

(a) amend the Milestone in agreement with the Subrecipient, provided that:

(i) either (A) the company support team provided by the PTE (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 Stage; or

(b) cease funding activities under the Subaward Agreement, in accordance with termination provisions identified in Face Page hereto, Terms and Conditions, Article 9 (48 CFR part 31.2).

Section 1.04 Deliverables.

(a) The Statement of Work describes the Budget and Milestones for this Subaward Agreement.

(b) This Subaward Agreement requires the Subrecipient to provide the PTE certain information and reports regarding the Project, including those described in Attachments 4, 5 and 6 ("Deliverables").

(c) The PTE is providing the Subrecipient with funding, as well as business and technical support services as agreed between the Parties, for the Project. The Subrecipient's success in completing the required Project tasks under each Stage (being the Base Stage and any exercised Option Stage) must be demonstrated to the satisfaction of the PTE through completion of the Statement of Work and Deliverables for that Stage.

(d) This Statement of Work in Attachment 5 may be extended, modified or terminated only as provided for in this Subaward Agreement.

Article II. Option Stages.

Section 2.01 No Automatic Option Stages.

(a) Unless an Option Stage is exercised in writing by the PTE as described herein, the Project consists only of the Base Stage. Any Option Stage will be the subject of a new Subaward

Agreement (in accordance with the process set out at Section 2.02).

Section 2.02 Option Stages.

(a) An Option Stage shall not be subject to exercise, and shall not be deemed exercised, unless the period of performance for the Option Stage falls within the approved project period of the PTE Federal and non-federal awards. Exercise of an Option Stage shall further require and be subject to each of the other requirements in this Section 2.02 below.

(b) The PTE will evaluate whether or not Milestones and Deliverables have been achieved to the PTE's satisfaction at the completion of the Base Stage, at each subsequent Option Stage or by mutual agreement.

(c) The PTE has no obligation to exercise any Option Stage and has no obligation to reimburse the Subrecipient for any work under any Option Stage, unless each of the following occurs:

(i) all of the specified Milestones and Deliverables are fully satisfied by the intended dates as set out in this Subaward Agreement, to the satisfaction of the PTE;

(ii) the CARB-X Joint Oversight Committee, in its sole discretion, chooses to fund the Option Stage; and

(iii) the Subrecipient and the PTE agree on a Statement of Work and budget to be incorporated as Attachment 5 for the Option Stage, evidenced in a fully-executed, new Subaward Agreement.

(d) Notice of intent to exercise an Option Stage shall be provided in the following manner:

(i) The PTE will give the Subrecipient written notice through the CARB-X Post-Award Advisory Board process for the Subrecipient's Project that a prospective Option Stage is being reviewed, subject to Section 2.02(c);

(ii) The PTE will endeavor to give the Subrecipient written notice of the PTE's intent to exercise an Option Stage within thirty (30) days following the Post-Award Advisory Board meeting for the Subrecipient's Project, subject to Section 2.02(c)(ii); and

(iii) After such notice of intent to exercise an Option Stage is given, the PTE will engage in negotiations with the Subrecipient to come to agreement on a new Statement of Work and budget to be incorporated into a new Subaward Agreement (which is materially in the same form as this Subaward Agreement) pursuant to Section 2.02(c)(iii).

Article III. Monitoring.

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

(a) In quarterly programmatic and monthly financial reports provided by the Subrecipient to the PTE on the CARB-X Digital Resources as detailed in Attachment 4 (Research Subaward Agreement Reporting Requirements);

(b) In the course of regularly scheduled meetings (at least once per quarter) with the Company Support Team;

(c) By the Subrecipient's Scientific Advisory Board (the "SAB");

(d) By the Subrecipient's ad hoc reports reasonably requested by the PTE or as detailed in Attachment 4a; and

(e) By a written Subrecipient report provided to the PTE when the Subrecipient determines it has completed a Milestone, in consultation with the Company Support Team.

Section 3.02 Subrecipient SAB and Company Support Team

(a) The Subrecipient shall establish (or shall demonstrate that it has already established) an SAB within sixty (60) days of executing the Subaward Agreement and the SAB shall continue to meet regularly during the Term. The Subrecipient will inform the PTE 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 the PTE and its funders.

Article IV. Subrecipient Representations and Warranties.

Section 4.01 The Subrecipient makes the following representations and warranties:

(a) The Subrecipient has all requisite power and authority to execute, deliver, and perform this Subaward Agreement and to deliver the Project.

(b) The Subrecipient has obtained or will obtain all third-party approvals and consents required for the Subrecipient to execute, deliver, and perform this Subaward Agreement where failure to obtain such approvals and consents would have a material adverse effect on the Subrecipient's ability to perform its obligations under the Subaward Agreement.

(c) The execution and performance of this Subaward Agreement by the Subrecipient does not and will not violate or conflict with, as applicable, the Subrecipient's charter documents, contract(s) or intellectual property agreements to which the Subrecipient is a party, which violation or conflict would have a material adverse effect on the Subrecipient's ability to perform its obligations under the Subaward Agreement.

(d) The Subrecipient will perform the Subaward Agreement and the Project in compliance with all applicable laws.

(e) All written statements made by the Subrecipient to the PTE during the application process, including Expressions of Interest, Short Form and Long Form Applications, Presentations to the CARB-X Advisory Board, written responses to the Funding Award – Due Diligence Form, Deliverables, and all other communications relating to this Subaward 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 Subaward Agreement; (b) as of the date any Option Stage is exercised; and (c) as of the date of any other written statement or verbal communication, when made to the PTE.

Article V. Additional Subrecipient 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 Subrecipient 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 Subrecipient is preparing a Product that is not a therapeutic or preventative for First Approval as defined in

Section 5.01(d) below), the Subrecipient shall create and provide to the PTE 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 Subrecipient shall update the Stewardship and Access Plan and provide it to the PTE 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 Subrecipient 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 PTE website.

(f) Obligations Follow the Product

(i) If control of the Subrecipient's Project IP Rights resulting from the Project changes, whether through sale, transfer, license, assignment or otherwise, the Subrecipient 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 Subrecipient to the PTE of any such event. If the Acquirer accepts obligations under Sections 5.01, 5.03 and 6.04, the Subrecipient is discharged from further obligations from Sections 5.01, 5.03 and 6.04.

(ii) If the Subrecipient fails to provide the Stewardship and Access Plan as provided in Section 5.01, within ninety (90) days, the PTE 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 Subaward Agreement and shall continue in force until the expiration of the last patent or exclusivity periods in the United States, the European Union or Japan for any Project IP Rights (the "Project IP Expiration").

(g) If the PTE informs the Subrecipient that it is no longer receiving CARB-X funding and no longer operates CARB-X, then Wellcome Trust will assume the rights reserved to the PTE in this Section 5.01, and, for purposes of this Section 5.01, the Wellcome Trust is an intended third-party beneficiary of this Subaward 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 Subrecipient 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 Subrecipient will make available any publications of research funded by CARB-X through PubMed Central (PMC) and Europe PubMed Central as soon as possible and in any event no later than six months from the date of final publication (in accordance with the Wellcome Trust's Open Access policy: https://wellcome.ac.uk/funding/managing-grant/open-access-policy, and the ASPR Public Access Plan: https://www.phe.gov/Preparedness/planning/science/Documents/AccessPlan.pdf).

(d) The Subrecipient will provide the PTE with advance copies of all manuscripts related to the Project when they are submitted or re-submitted for publication. The PTE will have no role in the preparation, editing or approval of the manuscript. An unpublished patent application will not be deemed to be a manuscript for the purposes of this subsection (d).

Section 5.03 Research and Development Standards and Development Diligence.

(a) The Subrecipient shall comply with all of the following standards at all times during the Project:

(i) Item 2 in the Agency Specific Certifications & Assurances included in Attachment 2 (describing minimum U.S. government mandated standards for research with animals and humans);

(ii) Where the Subrecipient is undertaking research using non-human primates, cats, dogs or horses, the Subrecipient must also comply with the NC3Rs review guidelines;

(iii) Where the Subrecipient is undertaking research involving human participants, the Subrecipient is required to have the relevant regulatory and ethical approvals and appropriate governance mechanisms in place before such research begins, and comply with relevant terms of the PTE prime award as detailed in Attachments 2 and 2a, including the Clinical Terms of Award and with item 3 in the Agency Specific Certifications &

Assurances included in Attachment 2 (describing U.S. government regulations on human subjects research). It is the responsibility of the Subrecipient (not the PTE) 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. The PTE 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 Subrecipient's research protocol shall include proposals for any necessary post-research health monitoring related to a volunteer's participation.

(b) Development Diligence. Subrecipient 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), 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 Subrecipient, its assignee or its licensee after the five (5) years following the end of the Term, then the Subrecipient, its assignee or its exclusive licensee shall, with respect to such Project IP Rights, be subject to the Access Rights under Section 8.06. If Subrecipient 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), 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 Subaward 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 Subaward Agreement and shall continue in force for a period of 10 years.

Article VI. Intellectual Property.

Section 6.01 Subrecipient Use of the Powered by CARB-X Logo.

(a) For the limited purposes of the Subrecipient's participation in CARB-X relating to the Project, the Subrecipient 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 Subrecipient's full performance of the terms and conditions of the Subaward Agreement and **PROVIDED THAT** the Subrecipient shall cease to use the Logo where the conditions set out at subsections (i) and (ii) below apply:

(i) The PTE determines, in its sole discretion, that use of the Logo is either no longer accurate or appropriate, in any way misrepresents the Subrecipient's participation, or for any reason reflects negatively on the PTE or the PTE's other partners, collaborators, sponsors or grantees; or

(ii) the PTE, BARDA, NIAID or the Wellcome Trust request that the use of the Logo is discontinued.

(b) The Subrecipient's use of the term "Powered by CARB-X" shall be subject to CARB-X Brand Guidelines, as set forth in Attachment 6a.

(c) Any other use of the CARB-X name, its Logo, servicemarks 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 the PTE. Those to whom such permission is granted must agree that the PTE shall remain the final arbiter of the use of the mark or Logo.

Section 6.02 PTE Use of Subrecipient Logo.

The Subrecipient hereby grants the PTE and the institutions represented on the CARB-X Joint Oversight Committee permission and the right to use the Subrecipient's corporate logo (and other artwork as agreed to by the Parties), for presentations, the PTE 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 Attachment 6 of the Subaward, the Subrecipient shall provide written notice to the PTE 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 Subrecipient and third parties to sublicense, transfer, or otherwise exploit the Project IP Rights.

(b) The Subrecipient 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 Subrecipient all Project IP Rights.

Section 6.04 Project IP Rights and Strategy. All rights are subject in all cases to the provisions of the PTE NOA (Attachment 2a), applicable Federal laws and regulations governing patents and inventions, including government-wide regulations at 37 CFR part 401 (per 45 CFR 75.322(c)) 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"). The NOA, applicable U.S. laws and regulations are not superseded or limited by any additional special terms or conditions imposed on the Subrecipient 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 Subrecipient 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 Subrecipient's most recent Stewardship and Access Plan and will be updated by the Subrecipient 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 Subrecipient 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 Subrecipient 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 Subrecipient.

(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 Subrecipient 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 Subrecipient and the Wellcome Trust (or the Wellcome Trust's nominee);

2) A Subrecipient supply arrangement between the Subrecipient 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 Subrecipient 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 Subrecipient 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 Subrecipient'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 Subrecipient 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 Subrecipient 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 Subaward 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 Subaward Agreement and shall continue in force until the Project IP Expiration.

Article VII. Budget.

Section 7.01 Cost Share Principles.

(a) The Subrecipient will meet the full amount of cost share obligation as stated in Attachment 5 (the "Cost Share Obligation").

(b) The Cost Share Obligation must meet the requirements described in this Subaward Agreement.

(c) The Subrecipient shall use commercially reasonable efforts to reach an agreement with NIAID to utilize NIAID Preclinical Services ("PCS").

Section 7.02 Budget Reconciliation.

(a) At the end of the Base Stage and at the end of any exercised Option Stage(s), the Subrecipient and the PTE will perform a budget reconciliation to determine:

(i) Whether the Subrecipient fully met the Cost Share Obligation.

(b) If the Subrecipient does not meet the Cost Share Obligation in full, the PTE may withhold payment or demand a refund to recover the unmet Cost Share Obligation.

(c) In the event the Subrecipient exceeds the Cost Share Obligation, the PTE will not reimburse any amounts above the Cost Share Obligation.

Article VIII. Definitions.

All other capitalized terms are defined as described in the text of this Subaward Agreement.

Section 8.01 CARB-X Funders means HHS/ASPR/BARDA, the Wellcome Trust, HHS/NIH/NIAID, Bill & Melinda Gates Foundation, UK Secretary of State for Health and Social Care ("DHSC"), and Germany's Federal Ministry of Education and Research.

Section 8.02 Project IP Rights means all patents, know-how, and trade secret rights, in each case, to inventions that are conceived or first actually reduced to practice in the Subrecipient's performance of the Project during the Term.

Section 8.03 Practical Application means to manufacture in the case of a composition of product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

Section 8.04 Subaward Agreement means this Cost Reimbursement Research Subaward Agreement.

Section 8.05 Term refers to the Subaward Period of Performance as stated on the Cost Reimbursement Research Subaward Agreement (face page) unless the Subaward Agreement is terminated by PTE pursuant to the Cost Reimbursement Research Subaward Agreement (face page) Terms and Conditions #9, 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 PTE's notice to the Subrecipient of early termination.

Section 8.06 Access Rights means:

(a) The Subrecipient 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 Subrecipient, 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 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 Subrecipient, 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 Subrecipient, 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 Subrecipient, assignee or licensees.

(b) Exercise of 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 Subrecipient, its assignee or exclusive licensee, as applicable, in writing of the information and request informal written or oral comments from the Subrecipient, its assignee or exclusive licensee as well as information relevant to the

matter. In the absence of any comments from the Subrecipient 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 Subrecipient, its assignee or exclusive licensee, in writing, that it will not pursue Access Rights on the basis of 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 Subrecipient 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 Subrecipient 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 Subrecipient, 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 Subrecipient, 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 Subrecipient, 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 Subrecipient, its assignee or exclusive licensee upon request. The requirement for a transcribed record may be waived by mutual agreement of the Subrecipient, 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 Subrecipient, 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 Subrecipient, 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 Subrecipient, its assignee or exclusive licensee by registered or certified mail. The Subrecipient, 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 Subrecipient, 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 Subrecipient, 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 Subrecipient, 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 Subrecipient, assignee or exclusive licensee adversely affected by Wellcome Trust's final determination to exercise Access Rights under this Section 8.06 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 8.06(a) above, a determination by the Director or designee unfavorable to the Subrecipient (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 Subaward Agreement has been signed.

Attachment 6a
Research Subaward Agreement
Powered by CARB-X Logo and Brand Guidelines

We encourage the use of the Powered by CARB-X in all communications that serve to raise the profile of CARB-X in a positive manner and to raise awareness about its mission. Any use of the Powered by CARB-X Logo must be in accordance with the Sub-Award Agreement between the Company and Boston University.

The following are guidelines to assist in the graphic design of communications materials in which you would like to use the Powered by CARB-X Logo.

1. Display: In order to preserve the integrity of the Powered by CARB-X Logos, it is important that no other logos, type or other graphic elements infringe on its space. The minimum "clear space" around the Logo in all uses is equivalent to ½ the height of the Logo.
2. Background Color: The Powered by CARB-X Logo should always be used in color for online use, fully visible and displayed on a white background. The Powered by CARB-X Logo should be used in color for print applications unless the color version is not practical, in which case the Powered by CARB-X Logo can be reproduced in solid black on a white background. For all other uses, such as in videos and digital communications, please consult with your CARB-X liaison for guidance prior to distribution or publication.
3. The Powered by CARB-X Logo should be displayed in high resolution as appropriate to the medium.
4. Do not use the Powered by CARB-X Logo in a manner that might create confusion as to the CARB-X brand or imply that CARB-X is the source of your products or services.
5. The Powered by CARB-X Logo must not be used as your own product names, service names, trademarks, logos, company names, domain names, website title, application icon, favicon, or the like.

Attachment 7
Research Subaward Agreement
Long Form Application

Long Form Application "pinned" below

(double-click to open):

Attachment 8
Research Subaward Agreement
Non-federal Sponsor Terms & Conditions

Bill & Melinda Gates Foundation ("Foundation")
Additional Terms

PUBLICATION

In addition to the requirements detailed in Attachment 2/Special Terms and Conditions #5 and Attachment 6/5.02, if Subrecipient 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. Subrecipient will mark any such publication subject to this clause with the appropriate notice or attribution, including author, date and copyright (*e.g.*, © 20<> <Name>).

INDEMNIFICATION

If the Subaward Scope of Work involves clinical trials, trials involving human subjects, post-approval studies, field trials involving genetically modified organisms, experimental medicine, or the provision of medical/health services ("Indemnified Activities"), Subrecipient will indemnify, defend, and hold harmless the PTE and Foundation and their respective trustees, employees, students and agents ("Indemnified Parties") from and against any and all 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 the acts or omissions, actual or alleged, of Subrecipient or Subrecipient's employees, subgrantees, subcontractors, contingent workers, agents, and affiliates with respect to the Indemnified Activities. Subrecipient agrees that any activities by the PTE or Foundation in connection with the Subaward Scope of Work, such as its review or proposal of suggested modifications to the Subaward Scope of Work, will not modify or waive the PTE or Foundation'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. Subrecipient'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 Subaward will constitute an express or implied waiver of Subrecipient's governmental and sovereign immunities, if any.

INSURANCE

Subrecipient will maintain insurance coverage sufficient to cover the activities, risks, and potential omissions of the Subaward Scope of Work in accordance with generally-accepted industry standards and as required by law. Subrecipient will ensure Subrecipient's subgrantees and subcontractors maintain insurance coverage consistent with this section.

COMPLIANCE

If the Subaward Scope of Work involves any trial involving human subjects, Subrecipient 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 Attachment 2/Special Terms and Conditions #6 (Press Releases):

Foundation prior approval is required for (a) press releases or other public announcements regarding this Subaward; and (b) any other public use of the Foundation's name or logo. Subrecipient must submit advance copies to PTE PI 5 days before issuance to allow time for PTE coordination with Foundation to obtain necessary approvals.

Subrecipient and Subrecipient'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

Subrecipient 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

Subrecipient 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 Subrecipient 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

Subrecipient may not use Grant Funds to influence the outcome of any election for public office or to carry on any voter registration drive. Subrecipient 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

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

The UK Secretary of State for Health and Social Care ("DHSC")
Additional Terms

PUBLICITY, COMMUNICATIONS AND BRANDING

As a supplement to the requirements detailed in Attachment 2/Special Terms and Conditions #5 (Publications) and #6 (Press Releases) and Attachment 6/5.02:
Subrecipient will not make any announcement concerning the existence or contents of this Subaward without the prior written consent of DHSC (such consent not being unreasonably withheld or delayed), except as required by law, any governmental or regulatory authority, any court, or any other authority or competent jurisdiction. Where a formal public statement or press release in relation to this Subaward is required, PTE and DHSC shall work together to ensure that the publicity statements are coordinated in advance. Subrecipient must submit advance copies to PTE PI 5 days before issuance, to allow time for PTE coordination with DHSC to obtain necessary approvals.

Subrecipient shall not use the name, logo, trademarks or other brand collateral of DHSC without DHSC's prior written consent. Subrecipient must submit any requests for such approval to PTE PI, who will coordinate with DHSC to obtain necessary approvals. Subrecipients creating outputs with the support of DHSC funding will be required by PTE to recognize the support of DHSC, PTE, CARB-X and other CARB-X funders by including in all such outputs, publications, and other results that reference DHSC and PTE's support the following or similar acknowledgment to be coordinated by PTE and DHSC: "This work was carried out with financial support from the Global AMR Innovation Fund (GAMRIF) funded by the UK Government Department of Health and Social Care (DHSC)."

PROHIBITED USES, UNALLOWABLE COSTS

- Payments for activity of a political or exclusively religious nature
- Contributions in kind (i.e. a contribution in goods or services, as opposed to money. Note: contributions in-kind are allowable to meet federal cost-share.)
- Entertaining (entertaining for this purpose means anything that would be a taxable benefit to the person being entertained, according to current UK tax regulations, including meals)
- Contributions will not, unless approved by DHSC in writing, be used to meet the cost of any import, customs duties or any other taxes or similar charges, applied directly or indirectly, by national Governments or by any local public authority on the goods / services provided. Subrecipient must submit any requests for such approval to PTE PI, who will coordinate with DHSC to request necessary approvals.
- Patent application costs (Note: expense may be allowable using other CARB-X funding sources)

FRAUD AND CORRUPTION

Subrecipient will immediately and without undue delay inform PTE PI of any event which interferes or threatens to materially interfere with the successful implementation of the Subrecipient Scope of Work, including credible suspicion of or actual fraud, corruption or any other financial irregularity or impropriety ("Financial Impropriety").

PTE will, at first, take timely and appropriate action to investigate credible allegations of fraud and Financial Impropriety in connection with the Subrecipient Scope of Work, immediately inform DHSC of the steps being taken to investigate the suspicion, and keep DHSC informed about the progress of the investigation. Subrecipient will fully co-operate with investigations into such events, whether led by PTE or DHSC.

In the event of any credible indications that DHSC funds may have been subject to Financial Impropriety, PTE and DHSC, may, at any time during the period of this Subaward and up to three years after the end of the

Subaward, arrange for additional fraud investigations, on-the spot checks and/or inspections to be carried out. These may be carried out by the PTE, DHSC, or any of their duly authorised representatives.

VULNERABLE POPULATIONS

Subrecipient will ensure that safeguarding policies and procedures to prevent unnecessary risk to vulnerable populations, including appropriate vetting of its employees involved in the Subrecipient Scope of Work, are carried out in accordance with good industry practice and following any reasonable instructions from PTE and DHSC.

ODA TRANSPARENCY

Subrecipient will provide assistance and information as needed for PTE to meet its ODA reporting (transparency) requirements, subject to the terms of the CARB-X Nondisclosure Agreement.

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

Additional Terms

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 Subrecipient are capped at the rate of US federal Executive Level II (see Subaward Attachment 2, Special terms and conditions).

However, if the Subaward is used to cover expenditure on staff or expenditure for general administrative purposes **and** if the total expenditure by the Subrecipient is covered mainly with German public funding, the Subrecipient 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 subrecipient, 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 Subaward Attachment 2, Special terms and conditions, 5-6).

Termination/Repayment

In the event that BMBF terminates PTE prime award, in whole or in part, PTE may terminate this Subaward Agreement, in whole or in part. PTE will terminate this Subaward Agreement in the case of credible fraud or serious misconduct including circumstances where the Subaward 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 Subaward is no longer being used for the intended purpose, or if a condition has arisen under which the Subaward Agreement becomes invalid.

In the event of termination, in whole or in part, the relevant portion of the Subaward 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).