Justification for Other than Full and Open Competition

41 U.S.C. 3304(a) (2)

Pursuant to the requirements of U.S. Code 41 U.S.C. 3304(a) (2) the Competition in Contracting Act (CICA) as implemented by Federal Acquisition Regulation (FAR), Subpart 6.302-2 and in accordance with the requirements of FAR, Subpart 6.303-1, the justification for the use of the statutory authority under FAR Subpart 6.3 is justified by the following facts and rationale required under FAR Subpart 6.303-2 as follows:

1. **Identification of the agency and contracting activity:**

   a. **Federal agency and contracting activity.**

   The Department of Health and Human Services (HHS), Food and Drug Administration (FDA), Office of Acquisition and Grants Services (OAGS).

   b. **Sponsoring organization.**

   Office of the Commissioner (OC), Office of the Chief Scientist (OCS), Office of Counterterrorism and Emerging Threats (OCET)

   c. **Contracting Officer's Representative (COR)/Requiring Activity Point of Contact (POC) information.**

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2. **Nature and/or description of the action being approved.**

   FDA/OC/OCS/OCET has an urgent requirement to modify existing FDA Ebola research contract number HHSF223201710194C with Public Health England (PHE) to develop a ferret challenge for 2019 Novel Coronavirus (2019-nCoV).

   On January 31, 2020, the Secretary of Health and Human Services (HHS) issued a Public Health Emergency Declaration pursuant to section 319 of the Public Health Service (PHS) Act "as a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV)". Following a section 319 declaration, the Secretary is authorized to take appropriate actions in response to the emergency including providing grants, entering into contracts; and conducting and supporting investigations into the cause, treatment, or prevention of the disease or disorder. An urgent requirement now exists for additional

research in order to aid in the development of effective medical countermeasures (MCMs) to combat this emerging threat.

PHE has a demonstrated and unique expertise in performing research and developing animal models with similar viruses and is the only known source that can undertake OCET's required research in a timely, safe and effective manner. This Contractor is known to have sufficient facilities to safely experiment and develop synthetic viruses, and the capability to document and deliver all research objectives within a compressed timeline. Due to this unusual and compelling urgency, it is not possible to evaluate alternate sources or award through full and open competition as this would create an unacceptable delay and seriously jeopardize the agency's ability to identify timely and effective MCMs under the current public health emergency.

a. Acquisition purpose and objectives.

The purpose of this acquisition is to rapidly leverage current expertise, facilities, agreements, and other resources currently under contract for Ebola study, in order to address a critical research need for medical countermeasure development in response to the emerging 2019 novel coronavirus (2019 n-CoV) as authorized by the Public Health Emergency Declaration of January 31, 2020. Given that FDA has an existing contract that entails the development and study of a ferret model for Ebola, the augmented scope for 2019-nCoV can be rapidly undertaken as it is a logical extension of the current capability. The Contractor, PHE, is the only known source that can conduct the required research in a timely and effective manner and also possesses unique expertise (including but not limited to 20 years of experience with this virus type and an appointment as a subject matter expert by the World Health Organization for this type of public health threat). This modification will enable FDA to urgently leverage this expertise as rapidly as possible to study nCoV and develop an animal model, which will be used in countermeasure development and licensing strategies.

Presently, a significant MCM development/regulatory gap exists from the absence of diverse animal models to support licencing efforts; although an approval strategy will likely utilize more standard methods (such as randomized clinical trials), the impact of animal models in pre-clinical/clinical work requires the establishment of a well characterized model.

By leveraging the current contract to execute the proposed research, FDA will be able to rapidly augment current activities underway in the characterization of Ebola infection (given that PHE is in process of developing/characterizing animal models, including ferrets), and use a similar technical approach to address this key gap for the current outbreak of coronavirus. This would facilitate a modified approach to nCoV that is not only likely to provide timely delivery of urgently needed information on the novel virus but will also leverage expertise that is not currently available elsewhere in the scientific community.

b. Project background.

Public Health England (PHE) was awarded FDA contract number HHSF223201710194C in 2017 for the total amount of $2,392,134 for the study of Ebola virus via FDA's broad agency announcement (BAA). The FDA BAA encourages participation by science and technology-based firms and educational institutions in meeting FDA goals for innovative ideas and approaches for regulatory

science. This project was selected for funding based in part on the expertise of the principle investigator, and the unique capabilities of the performer's facilities (which include international outreach and the capabilities to obtain samples from austere and otherwise inaccessible environments). The project has been executed to date without significant incurred risks or challenges. Furthermore, in FY2018, the FDA program office exercised both option periods for the contract, due to the need for the additional project objectives in response to an emerging Ebola outbreak, and the resulting need for additional animal model support in preparation for licensure considerations under the Animal Rule. While the coronavirus research can be conducted concurrently with the current (Ebola) tasks, an extension of 6 months will be required to enable all tasks to be completed, extending the period of performance through March 30, 2021.

The current outbreak of novel coronavirus constitutes a public health emergency in part due to the heretofore unknown aspects of the virus; among these gaps is the lack of a well-characterized animal model. Presently, the US Government is engaged in a multilateral effort to source and characterize viral isolates, however, it is unclear when (or if) these efforts will be successful; furthermore, the time required for obtaining isolates constitutes further delays to animal model development.

By contract, FDA has a unique capability by leveraging PHE's current effort under this 2017 contract, based on PHE's existing relationships, subcontracts, research facilities, and most notably expertise in coronavirus. Specifically, FDA intends to rapidly utilize the existing contract with PHE by expanding the animal model development/characterization to include coronavirus.

3. Description of the supplies or services required to meet the agency's needs (including the estimated value).

Objectives: Under this modification, PHE will leverage existing capabilities under the contract to complete several urgent objectives to support the public health response to the 2019 novel Coronavirus (2019-nCoV). These objectives were identified in coordination with FDA scientists to support FDA's public health mission:

Objective 1: PHE shall support the development of a ferret challenge model for 2019-nCoV.

Based on prior work in the development of animal models (specifically the SARS coronavirus ferret model development), PHE shall access the suitability of a ferret challenge model for growth and characterisation of 2019-nCoV. Development of this animal model shall be conducted in consultation with FDA and interagency stakeholders. All data from the development and experimentation with the model shall be made available to the research community, including the use of transcriptomics and subsequent analysis to identify biomarkers of interest and to compare this to known human data for 2019-nCoV. The deliverable from this activity will be a complete manuscript due no later than 28 February 2021.

The additional Coronavirus work is estimated at $250,250.00. Contract HHSF223201710194C expires September 30, 2020 and US FDA will seek a six (6) month extension to the services under this contract through March 30, 2021 to accommodate for the additional Coronavirus work.

a. Project title.

Development of a ferret challenge model for 2019 novel coronavirus (2019-nCoV)

Requirement type.

☒ Research & Development (R&D)

Type of action.

☒ Follow-on

Proposed contract/order type.

☒ Cost-plus-fixed-fee

Acquisition identification number.

Modification P0004 to contract HHSF223201710194C

b. Total estimated dollar value and performance/delivery period.

Base contract: $1,460,342M
Option 1: $400,607
Option 2: $531,185
Modification: $250,000
Total (Base and Modification): $2,642,134

Total Period of Performance: September 30, 2017 through September 29, 2020. This modification also seeks to extend the period of performance through March 30, 2021.

4. Identification of the statutory authority permitting other than full and open competition. Check the applicable block below based on the acquisition circumstance.

Federal Acquisition Regulation (FAR):

☒ 6.302-2 Unusual and compelling urgency. This acquisition is conducted under the authority of United States Code (U.S.C.) 10 U.S.C. 2304(c)(2) or 41 U.S.C. 3304(a)(2).

5. Demonstration that the proposed contractor(s) unique qualifications or the nature of the acquisition requires use of the authority cited.

FDA is seeking to rapidly leverage PHE's unique and readily available expertise in Coronavirus to support the development of a ferret challenge model for 2019-nCoV, to include delivery of manuscripts for the methodology and characterization of the model. These deliverables are crucial in the development of validation of medical countermeasures, a likely precursor to clinical trials, and for subsequent licensure. FDA is seeking to leveraging the existing contract because this performer has unique qualifications to execute this work:

- Unique prior expertise and technical approaches for the development of a prior coronavirus model, specifically the SARS coronavirus ferret model.

- 20 years of experience (supported by publications) with coronavirus, and a technical approach for nCoV that is likely to succeed, based on similar (successful) methodology used in SARS virus.
- Access to high security (BSL3) facilities that are currently approved to work on nCoV. Other agencies/entities are processing approval for this capability, but PHE is the only facility currently with confirmed approval for this effort and therefore the only source that can meet the FDA's requirement on an urgent basis.
- Existing regulatory institutional knowledge: PHE is a government agency for the UK, which provides extensive expertise in government-wide responses for public health threats; this is crucial for understanding and adjusting technical approach during a public health emergency and was demonstrated in the response effort for the Ebola virus.

a. Name and address of the proposed contractor(s).

Public Health England
Porton Down
Salisbury, UK 620975

b. Nature of the acquisition and proposed unique qualifications of the contractor(s).

This is an urgent research requirement, to address a knowledge gap related to a previously unknown virus; addressing this gap will be crucial to better understanding the virus, and has practical applications to development and licensure. In order to rapidly address this requirement, the Contractor must have extensive expertise in working with similar viruses, sufficient facilities to safely experiment and develop synthetic virus, and the capability to document and deliver all research objectives within a compressed timeline (as indicated in the deliverables table for the amended SOW). Furthermore, the Contractor's demonstrated history of working with coronavirus and establishing an animal model (via the SARS model) is a significant benefit to the Government as the effort follows a documented process that is more likely to succeed. The Contractor has an existing contract with FDA to complete similar development/characterization of a model for another high-risk viral pathogen (Ebola Virus), and have demonstrated their ability to complete these activities over the course of the existing contract. In order for the technical approach to succeed in an urgent and timely manner, the use of the existing contract leverages the following unique research assets which are readily available:

- PHE's subcontractor at the University of Liverpool hosts one of the major nodes for sequencing in the UK with both Illumina (MiSeq, HiSeq and NovaSeq), PacBIO and MInION sequencing. This equipment and facility will streamline sequencing of the 2019-nCoV to ensure timely delivery to FDA.
- The Hiscox laboratory has both UK Home Office approval and National Counter Terrorism Security Office (NaCTSO) to research and store nucleic acid from Category A agents as well as permission to use Schedule 1 toxic agents. This is a unique capability which is needed given the biosafety considerations of working with this virus and there is no other source with an approved facility readily available to meet the FDA's urgent needs.

PHE furthermore has access and approval to immediately begin work on the FDA's Coronavirus research. This has been an ongoing process across other research entities and the impacts to delivery schedule from these other entities would present an unacceptable risk. For these reasons, leveraging PHE's unique capabilities is crucial in the timely completion of the amended work. Presently, no other research performer is currently identified/available with the qualifications, expertise, and facilities to complete this work. Concurrent efforts are primarily focused on obtaining virus isolates, which are encountering challenges that preclude a confirmed delivery timeline. No work stream or timeline has been identified for other animal model development As such, this is a unique approach and can only be conducted by PHE.

6. **Description of efforts made to ensure that offers are solicited from as many potential sources as is practicable, including whether a notice was or will be publicized as required by subpart 5.2 and, if not, which exception under 5.202 applies.**

The response to the 2019-nCoV has been international in scope, including public health agencies from countries around the globe. However, international coordination for a response is still in initial stages, given the recent emergence of the virus. Furthermore, while information sharing has been successful to the extent that response efforts are coordinated, challenges (specifically for obtaining virus isolates) are being experienced by all responding parties and, a critical gap was identified in the interagency for the development of an animal model. While development of an animal model for the 2019-nCoV has been identified as a research need by multiple US agencies responding to this outbreak, there are no other confirmed plans for the development and delivery of an animal model with a known, clear and feasible schedule. By modifying PHE's existing contract, FDA will accomplish this urgently needed task while ensuring delivery in the most expeditious means available.

PHE's contract number HHSF223201710194C was awarded under the FDA's Broad Agency Announcement (BAA) program. The FDA BAA encourages participation by science and technology based firms and educational institutions in meeting FDA goals for innovative ideas and approaches for regulatory science. Organizations with interest in providing similar research are invited to submit White Papers for evaluation within the framework of the BAA and this process promotes innovation and competition amongst the scientific community. Any organizations submitting White Papers through the BAA program will have their concepts evaluated for further consideration and possible future awards. Additionally, OCET continually conducts market research to develop additional sources for support of program objectives.

This proposed action is made under the authority of FAR 6.302-2 and due to the unusual and compelling urgency of this requirement, the Government cannot comply with the 15 day positing requirement for this solicitation.

7. **Determination by the Contracting Officer that the anticipated cost/price to the Government will be fair and reasonable.**

The total value of this modification does not meet the threshold for requiring certified cost or pricing data at FAR 15.403-4(a)(1). The Contractor provided other than certified cost and pricing data to support their proposed price of $250,000.00 to complete this additional coronavirus research, including "[redacted]" ([redacted]) and fringe rates

established at "[redacted]"
([redacted]). This is consistent with the methodology used at contract award. PHE has also provided their current rate agreement with HHS, and their proposed indirect cost rate of [redacted] was audited and approved by HHS in August, 2019.

The proposed level of effort for this modification aligns with the required subject matter expertise and objectives. The proposed methodologies are logical, and timelines are sufficient and realistic to complete the work in an accelerated manner to meet FDA requirements. The program office's total IGCE for this modification is $250,000.00. While there are some deviations in the individual cost elements in the PHE modification proposal as compared to the IGCEs (i.e., higher and lower), the overall total costs for both modifications is equal to the IGCE amounts of $250,000.00 and is therefore determined to be fair and reasonable in accordance with FAR 15.405(b).

8. Description of the market research conducted (see FAR Part 10) and the results, or a statement of the reasons market research was not conducted.

With the international scope of the current 2019-nCoV response, the program office has completed an analysis of existing research assets (including the subject contract for modification), in conjunction with critical research needs. Based on this analysis, modification of the current contract is the only way to ensure that objectives will be met with sufficient timing for FDA to develop an animal model in response to this outbreak. Given PHE's unique qualifications and facilities to complete this work, market research is relatively limited as no other performers were identified with the combination of expertise and facilities to reasonably complete the objectives.

9. Any other facts supporting the use of other than full and open competition.

Pursuant to the Secretary of HHS's January 31, 2020 public health emergency declaration, FDA urgently requires a Contractor to rapidly develop a ferret challenge model for 2019-nCoV, to include delivery of manuscripts for the methodology and characterization of the model. Through ongoing engagement with the scientific community, FDA has determined that there is only one source with the required expertise in Coronavirus, with the existing partnerships, facilities and overall capability to perform this research.

If FDA were to pursue this requirement with unknown alternate sources, unacceptable delays would be incurred, as the performer would be compelled to establish research partnerships to obtain viral data, identify facilities with sufficient biosecurity to complete the work, obtain permission to utilize that facility, and develop logistics to sufficiently deliver objectives to the FDA. The Contractor would also need extensive expertise in working with similar viruses and the capability to document and deliver all research objectives within a compressed timeline. PHE is the only source known to have these capabilities readily available through its existing contract with FDA to complete similar characterization of another high-risk viral pathogen (Ebola Virus). PHE has demonstrated their ability to complete these activities over the course of the existing contract and shall provide all deliverables for the additional Coronavirus work no later than February 28, 2021. The estimated value of the additional Coronavirus animal model proposed under this modification is $250,250.00.

Any attempts to solicit and evaluate alternate sources for this research would seriously injure the FDA's ability to rapidly address the emergent public health threat of the coronavirus which has become a crisis in other parts of the world. Part of FDA's mission is to foster the development and research of medical products, including countermeasures, to respond to deliberate and naturally emerging public health threats. The FDA's ability to rapidly engage known research partners with documented research expertise is vital in accomplishing that mission. The delays which would be incurred in the solicitation and evaluation of new and untested alternate sources in a field of research of this type would create damaging and unacceptable delays in the FDA's ability to respond to the current public health emergency declaration of January 31, 2020. Furthermore, if a contract were to be awarded to alternate sources, the delays of evaluating the acceptability of any research deliverables from new sources would seriously injure FDA's ability to advance this research as there is no guarantee that another source can provide acceptable research deliverables post award. This would be a worst-case scenario and would put FDA's ability to respond to this emergent health threat in jeopardy. The costs associated with any delays under this scenario cannot be accurately estimated but would create an unacceptable risk to the FDA's ability to accomplish its mission.

At the conclusion of the proposed additional Coronavirus research under this effort, the FDA will then make a determination on the next steps, including any continuation. During this time, the FDA will continue to conduct market research for research partners in this field while also encouraging organizations to submit White Paper research proposals for the FDA's evaluation through the agency's BAA which is available to all interested organizations.

10. Listing of sources, if any, that expressed, in writing, an interest in the acquisition.

No other sources have expressed an interest, in writing, in the proposed acquisition.

11. Statement of the actions, if any, the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the required supplies or services.

Under the current circumstances (i.e. a public health emergency requiring urgent development of deliverables and targeted knowledge products), it is unclear if any further actions could be done to expand potential sources in the future. However, the FDA BAA remains a viable means for alternate offerors to provide submissions and technical concepts to address numerous medical countermeasure needs, including the possibility of conducting rapid research for emerging threats.

12. Program office certification.

This is to certify that the portions of this justification that have been developed by the undersigned program office personnel, including supporting information and/or data verifying the Government's minimum needs, schedule requirements and other rationale for other than full and open competition, are accurate and complete.

Signature: Robert P. Orr -S Digitally signed by Robert P. Orr -S Date: 2020.02.25 11:05:50 -05'00'

Robert Orr

Requiring Activity POC

Signature: Tracy C. Macgill -S3 Digitally signed by Tracy C. Macgill -S3 Date: 2020.02.25 13:21:55 -05'00'

Tracy MacGill

COR/POC Immediate Supervisor

Signature: Estella Z. Jones Digitally signed by Estella Z. Jones -S Date: 2020.02.25 16:09:54 -05'00'

Estella Jones

Head of the Sponsoring Program Office

13. Contracting Officer Certification.

This is to certify that the justification for the proposed acquisition has been reviewed and that to the best of my knowledge and belief the information and/or data provided to support the rationale and recommendation for approval is accurate and complete.

Signature: Richard W. Robinson -S Digitally signed by Richard W. Robinson -S Date: 2020.02.25 17:04:53 -05'00'

Richard Robinson

Contracting Officer