Office of Biomedical Advanced Research and Development Authority (BARDA) Division of Research, Innovation & Ventures (DRIVe)

Special Instructions 002 Issuance for Easy Broad Agency Announcement (EZ-BAA) BAA-20-100-SOL-0002

New Topic under Area of Interest (AOI) #4: 2019-nCoV

DRIVe Contracting Office
200 C Street SW
Washington, DC 20201

I. INTRODUCTION AND OVERVIEW INFORMATION

A. Development Opportunity Objective:

Under these Special Instructions 002, BARDA is adding a new topic under its temporary AOI #4: 2019-nCoV as part of its EZ-BAA (BAA-20-100-SOL-0002). We are now seeking abstract submissions for the following:

AOI #4.1: Molecular Diagnostic Assay for 2019-nCoV

The development and Emergency Use Authorization (EUA) of an *in vitro* diagnostic assay for the detection of 2019-nCoV RNA in clinical specimens, including upper (e.g, nasopharyngeal and oropharyngeal swabs, nasopharyngeal wash/aspirate, or nasal aspirate) and lower (e.g., bronchoalveolar lavage, tracheal aspirate, or sputum) respiratory tract specimens.

The assay must be developed for use with an existing FDA-cleared molecular platform that is currently widely placed in U.S. healthcare settings. Respondents should present a viable plan that achieves an EUA submission milestone within 12 weeks of award. As part of the abstract submission, respondents should describe the current development status of their 2019-nCoV assay, including *in silico* analysis of targets, access to validation materials to support EUA submission, and contacts with the FDA.

AOI #4.2: Nonclinical Model Development and Screening for 2019-nCoV

The development of an *in vitro* assay and *in vivo* 2019-nCoV nonclinical model(s) for screening potential medical countermeasures for the treatment of 2019-nCoV.

Respondents must possess a 2019-nCoV strain, hold a Select Agent Permit, and have access to a nonclinical BSL-3 laboratory capable of performing mouse therapeutic studies of 2019-nCoV. As part of the abstract submission, respondents should describe the current development status of their 2019-nCoV assay, justify species to be used for *in vivo* screening, and demonstrate recent *in vivo* work with therapeutics for SARS-CoV and MERS-CoV.

B. Eligible Respondents & Scope Parameters:

These Special Instructions 002 are open to all responsible sources as described in the EZ-BAA. Preliminarily, a call with the relevant Program Manager is strongly encouraged prior to any submission to better understand the program objectives for AOI #4. The points of contact for each topic under AOI #4 are the following:

AOI #4.1: John Lee, john.lee@hhs.gov
AOI #4.2: Brian Tse, brian.tse@hhs.gov

AOI #4 will be open for abstract submissions until 1700 HRS ET on 18 March 2020, unless otherwise extended. Additionally, award(s) expected to be made under these Special Instructions 002 will be less than $750,000 in total government funding.

Abstract submissions that do not conform to the requirements outlined in the EZ-BAA may be considered non-responsive and will not be reviewed.

NOTE: Funding is limited, so we encourage any interested vendors to reach out to the appropriate Program Manager listed above before submitting an abstract as soon as possible.

C. Number of Awards:

Multiple awards are anticipated and are dependent upon the program priorities, scientific/technical merit of submissions, how well submissions fit within the AOI, and the availability of funding. The program funding is subject to change based on the government's discretion.

D. Special Instructions Application Process:

These Special Instructions 002 will follow the same submission process and review procedures as those established under the EZ-BAA. For complete details, please read the EZ-BAA solicitation in its entirety.