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

Special Instructions 001 Issuance for Easy Broad Agency Announcement (EZ-BAA) BAA-20-100-SOL-0002

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, BARDA is temporarily suspending AOIs 1-3 as part of its EZ-BAA (BAA-20-100-SOL-0002), but is pleased to announce that it is now accepting abstract submissions for AOI #4: 2019-nCoV. We are seeking abstracts for the following under this focus area:

1. 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.

B. Eligible Respondents & Scope Parameters:

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

John Lee - john.lee@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 will be less than \$750,000 in total government funding.

Abstract submissions that do not conform to the requirements outlined in the EZ-BAA (BAA-20-100-SOL-0002) may be considered non-responsive and will not be reviewed.

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 area of interest, 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 will follow the same submission process and review procedures as those established under the EZ-BAA (BAA-20-100-SOL-00002). For complete details, please read the EZ-BAA solicitation in its entirety.