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Dated: August 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Biomedical Advanced Research and Development Authority (BARDA)

AGENCY: Assistant Secretary for Preparedness and Response, HHS.

ACTION: Notice.

SUMMARY: The Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR), in the Department of Health and Human Services intends to provide a Single Source Cooperative Agreement to Janssen Research & Development, LLC. The Cooperative Agreement will support QuickFire Challenges to spur innovation in respiratory protection. The total proposed cost of the Single Source Cooperative Agreement is not to exceed \$100,000 for a total of 12 months.

DATES:

Project Period: The period of performance is from July 30, 2018 to June 30, 2019.

Award amount: Estimate \$100,000.

FOR FURTHER INFORMATION CONTACT:

Sherrette.Funn@hhs.gov, 202–795–7714, *Julie.Schafer@hhs.gov*, 202–205–1435.

SUPPLEMENTARY INFORMATION: The Biomedical Advanced Research and Development Authority (BARDA) is the program office for this Cooperative Agreement:

Single Source Justification: Janssen Research & Development, LLC creates global challenges to spur innovation in health care in partnership with JLABS, a global network of open innovation ecosystems designed to support innovators and entrepreneurs in creating and accelerating innovative health care solutions.

Janssen Research & Development, LLC and BARDA will collaborate on a global challenge for reimagined, transformative respiratory protection. Traditional respiratory protective devices used to protect against inhalation of harmful infectious agents were designed for use in occupational settings, to guard against inhalation of dangerous particulates. Disposable versions, such as N95 respirators, are only available for adults, must be fit-tested to ensure proper functioning, and can be uncomfortable to wear. In an outbreak of a novel or newly emerging respiratory

disease, respiratory protection may be the only countermeasure available to protect health care workers and the general public.

Janssen Research & Development, LLC will partner with JLABS, which exists to foster innovation in health care products and executes QuickFire Challenges for health care innovation. There is no direct equivalent of the QuickFire Challenge services for innovation specific to health care as is provided by JLABS. Its unique service will directly benefit BARDA’s mission to make available medical countermeasures to address health security threats. Supporting innovation is an authority provided to BARDA under the Public Health Service Act and partnering with a company providing a diverse array of products and leveraging its expertise and infrastructure has the potential to provide solutions to the challenges in developing new respiratory devices.

Reimagined, innovative respiratory protection would contribute directly to ASPR’s mission to save lives and protect Americans against 21st Century health security threats. Respiratory protection is often the first line of defense, and a radically improved approach to protect both health care workers and the general public, including children, would truly improve our ability to respond to public health emergencies. By generating interest and focusing innovation efforts on reimagining respiratory protection, BARDA’s goal for the QuickFire Challenge is for the resulting innovative approaches to be eligible for continued testing and development and eventual regulatory approval, so that these revolutionary products can be widely available and used.

Please submit an inquiry via the ASPR–BARDA Program Contact: Dr. Julie Schafer, *Julie.Schafer@hhs.gov*, 202–205–1435.

Robert P. Kadlec,

Assistant Secretary for Preparedness and Response.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Pain Management Best Practices Inter-Agency Task Force

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.