

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Biomedical Advanced Research and Development Authority (BARDA)

Division of Research, Innovation, and Ventures (DRIVE)

Plans for Mask Innovation Challenge Request for Information

PURPOSE: BARDA DRIVE is seeking to understand and develop tools such as challenges and prize competitions that the Federal government and others can use to engage a broad range of stakeholders, including the general public, in developing solutions to difficult problems. Challenges and prize competitions rely on competitive structures to drive innovation among participants and usually offer rewards (financial and/or other) to winners and/or finalists. BARDA may use the information submitted from interested parties to develop challenges and prize competitions to address key respiratory device-related issues. BARDA DRIVE is not soliciting input on BARDA's broader R&D efforts on COVID-19 or other programs.

BACKGROUND: The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary of Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS) serves the nation by partnering with industry to make available medical countermeasures against a wide range of major threats to our national health security. BARDA and our industry partners have been successful in delivering new therapeutics, vaccines, diagnostics and devices against serious health threats including chemical, biological, radiological, nuclear (CBRN) agents, pandemic influenza and emerging infectious diseases and their sequelae.

Respiratory pathogens, including Influenza and Coronaviruses, are known to spread by three main routes: mucosal contact of droplets, inhalation of smaller aerosolized particles, and fomite transmission. Multiple publications have now demonstrated the efficacy of surgical masks (and to an extent, cloth masks) in preventing droplets from breaths, coughs, and sneezes from spreading viral particles. These findings form the base of scientific evidence used by public health agencies worldwide for their citizens to wear masks when in public spaces to reduce the spread of the SARS-CoV-2 virus. However, while such masking practices are efficacious in preventing spread, they are less effective at protecting the wearer from infection and identified as a barrier to mask wearing.¹

There are significant design barriers that preclude individuals from wearing masks, such as contact dermatitis with prolonged wear, physical discomfort, difficulty communicating (due to impaired speaking and recognition of facial expressions), or breathing. In addition, many commonly-available masks on the market tout unconfirmed protective factors that lack scientific data to support such claims. Thus, there is a need to develop technologies that meet defined performance standards, while providing comfort and durability to the average consumer.

BARDA, in partnership with National Institute for Occupational Safety and Health (NIOSH), intends to launch the Mask Innovation Challenge, in early 2021, subject to the availability of funds and final agency approval. The competition is designed to support the development of improved mask designs and other related technologies that are more comfortable, have improved fit, and meet defined performance

¹Centers for Disease Control and Prevention. Scientific Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2 <https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html>

standards including protection to the wearer and also preventing some level of particles from escaping the mask. The competition is anticipated to run for up to one year and offer financial awards and in-kind support services for meeting the challenge goals.

We are particularly interested in your input on the following questions regarding the evaluation criteria and testing protocols for mask submissions:

DEVELOPMENT OF EVALUATION CRITERIA

1. What do you see as the most important criteria to evaluate the effectiveness of a community mask that is to be used by the general public? Examples might include: assurance of consistent fit, comfort, airflow resistance, ability to protect the wearer and stop particles from escaping the mask, cost, etc.
 - a. In addition, please provide feedback on the following evaluation criteria:
 - i. **Feasibility** – Submission demonstrates a reasonable rationale for the design of the mask, intuitive design that can be used without fitting or prior training, and contains components that are easily accessible.
 - ii. **Innovation**. Submission advances the state of the art in filtration efficacy, comfort, and utility of masks used by the general public.
 - iii. **Barriers**. Submission addresses barriers and limitations of currently available masks and proposed innovations are based on scientific and technical merit.
 - iv. **Design and Desirability**: Submission demonstrates how the proposed solution meets the needs of the users and shows how it could integrate into production now or in the future.

TESTING PROTOCOLS: Please provide feedback to NIOSH on the following questions regarding performance criteria and testing protocols for novel mask designs. **Please provide supporting rationale for any suggestions submitted.**

1. For the evaluation of novel mask designs in a laboratory setting, what performance criteria would you recommend and how would you structure a test? Examples might include: criteria for evaluation of fit factors, percent allowable particle penetration through the filter material, percent allowable particle concentration escaping the mask, maximum inhalation and exhalation airflow resistance, etc.
2. If BARDA were to require prototypes to be submitted for evaluation, how many individual prototype samples should be evaluated?
3. What other factors or experiences with general-use masks do you consider important to this mask challenge that you want BARDA and NIOSH to be aware of?

PARTNERSHIPS:

1. What sectors or stakeholders should BARDA engage as part of these efforts?
2. If there is an opportunity for sponsorship, is your organization interested in participating as a potential sponsor? If yes, what are the capabilities of your organization in support as a potential sponsor?
3. Would your organization be interested in joining a list of experts that may provide mentorship to challenge winners?

4. Would your organization be interested in serving as a marketing partner and provide marketing and outreach as part of the challenge competition including posting on websites, social media, and other outlets?

DATES: the period for comments begins with the publication of this document. Submissions must be received on or before 01/15/2021 to be considered.

SUBMISSIONS: Individuals are encouraged to submit responses electronically to DRIVEComments@hhs.gov. Please indicate "Mask Challenge Response" in the subject line of your email. Submissions received after the deadline may not be reviewed. Responses to this notice are not offers and cannot be accepted by the federal government to form a binding contract or issue a grant. Respond concisely and in plain language. You may use any structure or layout that presents your information well. You may respond to some or all of our questions, and you can suggest other factors or relevant questions. You may also include links to online material or interactive presentations. Clearly mark any proprietary information, and place it in its own section or file. By engaging in this process or submitting any information in relation to this RFI, interested parties acknowledge that federal and nonfederal U.S. Government personnel may participate in the process and provide input compliant with applicable law and regulation. All personnel are strictly bound by the appropriate non-disclosure requirements. Interested parties should not engage in any part of the announcement process if they do not consent to the participation of non-federal consultants as described in this subparagraph. Your response will become government property and the U.S. Government may publish some of its non-proprietary content.