Safe resumption of research is important, feasible

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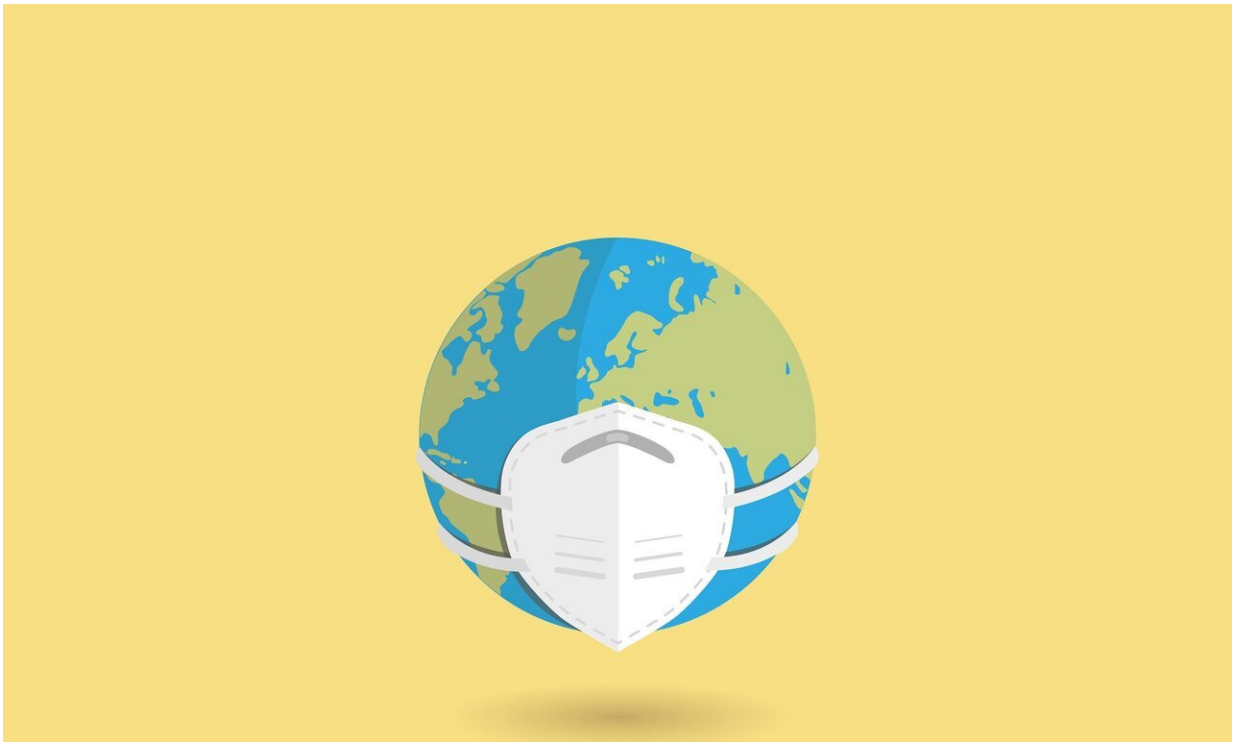

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At the onset of the COVID-19 pandemic, just as public institutions and businesses closed, research programs performing human participant research (HPR) also largely ceased operations. Now, universities and healthcare organizations conducting HPR are considering reopening.

While guidelines from federal and state government and medical specialty societies currently exist to help restarting health services and resuming clinical trials, no clear guidance is available to aid resumption of HPR at community-based, observational cohort studies.

In a narrative review in the *Journal of the American Heart Association*, researchers from the Boston VA Healthcare System and Boston University School of Medicine (BUSM), describe a potential path forward for safely reopening community-based observational studies, drawing on scientific knowledge and best practices from a variety of medical and lay sources.

"We outline a framework for how human subjects research can be potentially resumed during the pandemic while simultaneously ensuring the safety of human participants," explained corresponding author Raghava S. Velagaleti, MD, MPH, FSCAI, cardiologist at the VA and adjunct instructor of medicine at BUSM.

The researchers highlight current recommendations and useful metrics for guiding decisions regarding safe reopening/reclosing and for screening and surveillance of COVID-19 among employees and participants. They also suggest ways in which observational studies can potentially aid the efforts to characterize the pandemic.

According to the researchers, indefinite stoppage of observational research carries harms to society and the research enterprise in terms of new knowledge not generated and research programs that may fail, leading to wasted resources and unrealized gains. "Scientists and researchers are putting in considerable thought and effort into developing frameworks for ensuring the safety of research participants during the pandemic and mitigating the participants' likelihood of contracting COVID-19 because of their participation in research studies," said senior author Vasan Ramachandran, MD, FAHA, FACC,

professor of medicine at BUSM and director of the renowned Framingham Heart Study.

The researchers believe that their redesigned research policies and procedures and a cautious approach to reopening, make it possible to resume research while simultaneously mitigating risk to participants and staff. "Our suggested approach can be a potential path forward not just for current resumption of observational studies, but also reengineer them to improve research participant experience and cope with possible future infectious disease pandemics," added Velagaleti.

More information: Raghava S. Velagaleti et al. Restarting Human Participant Research at Community-based Observational Studies during the COVID-19 Pandemic, *Journal of the American Heart Association* (2020). DOI: 10.1161/JAHA.120.018832

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