



December 22, 2020

The Association of State and Territorial Health Officials
2231 Crystal Dr., #450
Arlington, VA 22202

RE: COVID-19 Vaccine Distribution Access for Clinical Research Professionals

To Mr. Fraser and Mr. Plescia:

The Association of Clinical Research Organizations (ACRO,) the Society for Clinical Research Sites (SCRS,) and the Association of Clinical Research Professionals (ACRP,) thank the The Association of State and Territorial Health Officials and its members for your work and appreciate the opportunity to comment on a matter of great importance—plans for distribution of COVID-19 vaccines by the state health officials and governors. We write to ensure that certain essential healthcare professionals not be inadvertently omitted from the cohort prioritized for early vaccine access.

Our organizations represent companies and research professionals that conduct or support the conduct of approximately two-thirds of all clinical trials in the United States and deploy more than 50,000 people who provide critical services at clinical trial sites. This includes nurses, laboratory and medical technicians, clinical research coordinators and research associates who monitor trials. Our members are involved with all aspects of clinical trials, including but not limited to: feasibility studies, protocol design, patient recruitment, obtaining informed consent, administering trial procedures and interventions, collecting scientific data, providing outside monitoring of the conduct of the trial, and ensuring patient safety and data integrity. Our members provide these services in academic medical centers, hospitals, medical practices, and dedicated research sites across all therapeutic areas. ACRO, SCRS and ACRP research professionals have been involved in all of the completed and continuing COVID vaccine trials, as well as over 500 clinical trials testing potential treatments for COVID-19.

As these professionals are working in hospitals and other medical facilities, including dedicated research sites, each day to manage and support the conduct of clinical research, it is essential that they have access to a vaccine in order to protect themselves, the clinical trial participants they are coming into contact with, and other patients at the site, including COVID-19 patients enrolled in studies or accessing medical care at the health facility.

As state health officials and governors develop their state guidelines to support and prioritize vaccine distribution for essential health professionals, **ACRO, SCRS and ACRP request that health research professionals providing essential services to clinical trials, including COVID-19 vaccine and treatment trials, as well as ongoing clinical trials and related activities in other therapeutic areas, be classified among the priority medical personnel who are critical to the nation's response to the pandemic.** The work of clinical research sites and professionals is, in fact, essential not only to those infected by COVID-19, but to the health of the nation's population.

Recognizing the medical professionals who conduct and support the conduct of clinical trials research as essential and providing them access to a vaccine will assist in ensuring that clinical trials in the United States



remain safe for all those involved, so that new biomedical products and treatments continue to reach the patients who need them in an efficient and timely manner.

Thank you for the opportunity to raise this important issue to your attention. Again, our organizations appreciate the work of the country's state health officials and governors during this extremely challenging time. Please do not hesitate to reach out if additional information from ACRO, SCRS, ACRP, or our members could be at all helpful.¹ ACRO's Director of Government Relations, Sophia McLeod, can be reached at smcleod@acrohealth.org and SCRS' Chief Operating Officer, Allyson Small, can be reached at allyson.small@myscrs.org. Jim Kremidas, Executive Director of ACRP can be reached at jkremidas@acrpnet.org

Sincerely,

Douglas J. Peddicord, Ph.D.
Executive Director, ACRO

Jim Kremidas
Executive Director, ACRP

Allyson Small
Chief Operating Officer, SCRS

¹ The Association of Clinical Research Organizations (ACRO) represents clinical research organizations and technology companies that support the conduct of a majority of FDA-regulated clinical trials around the world.

The Society for Clinical Research Sites (SCRS) represents 10,000 research sites worldwide and serves as the unifying voice of the clinical research site community.

With 13,00 members, the Association of Clinical Research Professionals (ACRP) supports clinical research professionals through membership, training and development, and certification.