



November 23, 2020

Dr. José Romero
Chairman
Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
1600 Clifton Road, NE, Mailstop A27
Atlanta, GA 30329-4027

RE: Docket No. CDC-2020-0117, Comments for the November 23, 2020, Centers for Disease Control and Prevention Advisory Committee on Immunization Practices Meeting

To The Advisory Committee on Immunization Practices:

The Association of Clinical Research Organizations (ACRO) thanks the Advisory Committee for its work and appreciates the opportunity to comment on a matter of great importance, the guidelines for distribution of COVID-19 vaccines as emergency use authorization applications are granted. We write to ensure that certain essential healthcare professionals not be inadvertently omitted from the cohort prioritized for initial vaccine access.

ACRO represents the world's leading clinical research and technology organizations. Our fourteen member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices—from pre-clinical, proof of concept and first-in-human studies through post-approval, pharmacovigilance, and health data research. ACRO member companies manage or otherwise support the majority of all biopharmaceutical sponsored clinical investigations worldwide. With more than 200,000 employees engaged in research activities in 114 countries, the member companies of ACRO advance clinical outsourcing to improve the quality, efficiency, and safety of biomedical research.

ACRO member companies conduct or support the conduct of approximately two-thirds of all clinical trials in the United States and deploy more than 25,000+ 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. This number does not include in-house sponsor or research site staff. ACRO member companies are providing clinical trial services to completed and ongoing COVID vaccine trials, as well as many of the more than 250 COVID treatment studies running around the world. As an example of the scope of these services, during the peak periods (patient enrollment) for each COVID-19 vaccine trial the number of clinical research associates (CRAs) deployed to monitor and support that trial ranges from 110-160 FTEs across the US.

Through their critical support functions, clinical research professionals protect the safety of trial participants and ensure the integrity of the data used to determine the safety and efficacy of new treatments and medical products. As these professionals are working in hospitals and other medical facilities 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, other patients at the site, including COVID-19 patients enrolled in studies or accessing medical care at the health facility.

As the ACIP advises the CDC on the development of guidelines to support and prioritize vaccine distribution for essential health professionals, **ACRO requests that health research professionals providing essential support 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.**

Recognizing the medical professionals who support clinical 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 comment. Again, ACRO appreciates the work the Committee has done on this extremely important topic. Please do not hesitate to reach out if additional information from ACRO or our members could be at all helpful. Our Director of Government Relations, Sophia McLeod, can be reached at smcleod@acrohealth.org.

Sincerely,



Douglas J. Peddicord, Ph.D.
Executive Director