



National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 30, 2020

Sidney M. Wolfe, MD
Founder and Senior Advisor
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

Dear Dr. Wolfe:

Thank you for your July 6, 2020, letter to me and Dr. Francis S. Collins, Director of the National Institutes of Health (NIH), regarding human coronavirus challenge studies. I am pleased to respond.

NIH is committed to safeguarding the health of Americans and people around the world by accelerating research efforts to address COVID-19. Efforts across NIH are underway to characterize the causative agent of this disease, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and to develop countermeasures to prevent, diagnose, and treat COVID-19. Building on previous research on coronaviruses, National Institute of Allergy and Infectious Diseases (NIAID) scientists and grantees are well positioned to rapidly develop COVID-19 diagnostics, therapeutics, and vaccines. These projects include conducting basic research to understand how the virus infects cells and causes disease, and pursuing interventions that can prevent and treat the infection.

Safe and effective vaccines will be a critical tool to prevent infection with SARS-CoV-2 and help to end the COVID-19 pandemic. NIH is participating in a whole-of-government effort to pursue the development of safe and effective SARS-CoV-2 vaccines as rapidly as possible. NIH currently is prioritizing randomized controlled clinical trials to evaluate the safety and efficacy of SARS-CoV-2 vaccine candidates. A number of candidates have entered clinical trials, with several of these poised to enter Phase 3 randomized controlled clinical trials. These trials are designed to provide information that may support licensure of the vaccines and availability to the public, should they provide evidence that the candidate is safe, immunogenic, and protective. Controlled human infection (CHI) studies are one research approach that might help determine the effectiveness of a vaccine. However, the best way to determine both safety and efficacy is through the current plan of conducting adequately powered, randomized, controlled trials.

I agree that CHI studies can raise significant ethical questions, and it is important that these questions be examined and carefully considered prior to undertaking such studies. If the randomized controlled trials prove infeasible for any reason, CHI studies, if able to be conducted safely and ethically, could be an important and scientifically sound complementary strategy to more traditional vaccine development approaches.

NIH has not yet made a determination about whether to support CHI studies. By the end of 2020, preliminary (and potentially final) data from SARS-CoV-2 candidate vaccine clinical trials described above would be available and would be used to inform the assessment of future SARS-CoV-2 human challenge studies. Should there be a need for CHI studies to assess candidate vaccines or therapeutic safety and efficacy for SARS-CoV-2, NIAID has begun early stage investigations of the technical, ethical, and community considerations of conducting such studies. Although NIH is prioritizing assessment of SARS-CoV-2 vaccine candidates through clinical trials, these early stage investigations of CHI studies would allow us to be prepared should they be deemed necessary and safe and ethical to employ.

Thank you for your interest in NIH's research programs. I hope this information is helpful to you. An identical response also has been sent to Mr. George Annas, the co-signer of your letter.

Sincerely,

A handwritten signature in black ink, appearing to read "A. Fauci", with a large, sweeping flourish extending to the right.

Anthony S. Fauci, M.D.
Director
National Institute of Allergy
and Infectious Diseases