



August 18, 2020

Thomas M. File, Jr., M.D., MSc, FIDSA
President
Infectious Diseases Society of America (IDSA)
4040 Wilson Boulevard
Suite 300
Arlington, VA 22203

Judith Feinberg, M.D., FIDSA
Chair
HIV Medicine Association (HIVMA)
4040 Wilson Boulevard
Suite 300
Arlington, VA 22203

Dear Drs. File and Feinberg:

Thank you for your July 29, 2020, email to Dr. Francis S. Collins, Director of the National Institutes of Health (NIH), concerning the exclusion of people with HIV from the Phase 3 trial of mRNA-1273 sponsored by Moderna. As the Director of the National Institute of Allergy and Infectious Disease (NIAID) Division of AIDS, I am pleased to respond.

When NIAID reviewed the original version of the protocol, the exclusion criteria did not specifically delineate people with HIV. However, when it was finalized, HIV had been added, creating a discrepancy with the inclusion criteria. We agree that there is no scientific reason to exclude people with HIV who receive antiretroviral therapy (ART) and are virally suppressed from the trial. Based on this and the concerns voiced by community, NIAID, the Protocol Chairs, and the team at Moderna have worked together to amend the protocol to reflect this. The protocol amendment has been submitted to the FDA for approval.

Please note that other COVID-19 Phase 3 vaccine and monoclonal antibody trials being conducted through the COVID-19 Prevention Network (CoVPN) and the treatment trials being conducted through Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative will include people with HIV who receive ART and are virally suppressed as participants. Building on the long-standing and critical community engagement efforts of the NIH-funded clinical trials networks and their community advisory boards (CABs), we have begun to develop a robust community engagement effort for our COVID-19 research. While those efforts are still evolving, both the CoVPN and ACTIV have established CABs. The CoVPN Community Working Group (CWG) was established using the HIV Prevention Trials Network (HPTN) and the HIV Vaccine Trials Network (HVTN) CABs as both a model and foundation. The CWG is comprised of community representatives who have been involved with one of those networks, as well as other new members. With respect to therapeutics trials, the AIDS Clinical Trials Group (ACTG) COVID-19 CAB is providing input on a Phase 2/3 clinical trial that will evaluate the safety and

efficacy of potential new therapeutics in outpatients with COVID-19 (ACTIV-2). This CAB includes individuals who have been working with the ACTG for years, as well as new members representing communities disproportionately impacted by COVID-19. Both the CoVPN and ACTIV-2 also have larger planning committees that are addressing broad communications, messaging, and outreach strategies to ensure racial, ethnic and culturally appropriate efforts to reach key populations.

To facilitate effective outreach to key communities, the CoVPN has also established a number of expert panels. These include Native American, Black/African American, Latinx and Older Adult expert panels, and other panels that are still being formed. These panels include 10-15 scientific experts from within their respective communities who will provide their insight and expertise on the protocol. The panels also will address issues related to ethics, the significance and potential impact of the research in their communities, and they will make recommendations for broader community engagement as appropriate. While the panels were established after the Moderna Phase 3 protocol was already finalized, they will have input on future studies.

Moving forward, we are taking steps to ensure that people with HIV receiving ART and virally suppressed can participate in future COVID-19 clinical studies and that community engagement and outreach are critical components of the COVID-19 research process.

Thank you for your continued support of and interest in NIAID research. I hope this information will be helpful to you.

Sincerely,

A handwritten signature in blue ink, reading "Carl Dieffenbach".

Carl W. Dieffenbach, Ph.D.
Director
Division of AIDS