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July 27, 2020

Francis S. Collins, MD, PhD
Director, National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Collins:

We, the undersigned organizations, urge you to ensure that the sponsors of COVID-19 clinical trials for COVID-19 treatment and prevention interventions do not exclude people living HIV. Our letter is occasioned by the exclusion of people with HIV in the mRNA-1273 Moderna Phase 3 COVID-19 vaccine trial according to [ClinicalTrials.gov](https://clinicaltrials.gov). We are extremely dismayed to learn that COVID-19 vaccine candidate developed with significant contributions from researchers at the NIH excludes people with HIV with no scientific basis. We want to be sure you are aware of this situation, will do everything in your power to intercede with Moderna to reverse this exclusion and ensure that such an exclusion never happens again. This matter is particularly urgent and requires your immediate attention as this trial opened to enrollment on July 27, 2020.

The Moderna mRNA-1273 [exclusion criteria](#) specifically cites people with “human immunodeficiency virus (HIV) infection.” This sets a terrible precedent, not grounded in any scientific data. If the Moderna vaccine is approved by the FDA, there will be no data on its safety or efficacy in people with HIV. Thus, there will probably not be an FDA indication for people with HIV or payer reimbursement as a result.

Although the inclusion criteria notes that adults with pre-existing medical conditions who are in stable condition are eligible, the fact that HIV is specifically stated in the exclusion criteria without further information infers that the note for adults with pre-existing medical conditions does not apply to them regardless of their health status. This must be clarified in all publicly available information for the Moderna trial with the protocol team and with all participating trial sites as well as on [ClinicalTrials.gov](https://clinicaltrials.gov).

There is no clinical justification for excluding people with HIV from COVID-19 vaccine trials. Thanks to the advent of triple combination antiretroviral therapy (ART) in the mid-1990s, HIV infection has not been synonymous with an “immunodeficient state” for over two decades. For this reason, routine immunizations are recommended for people with HIV, with the only caveat being withholding of certain live vaccines if the CD4 T count is below 200, [according to the CDC](#).

At most, CD4 T cell threshold criteria might be employed if there are concerns about people with very low counts being able to mount insufficient vaccine responses. If there are concerns about a unique immune response for people with HIV, this can be studied through a subset analysis of participants with HIV. This approach should be considered for participants with other controlled co-morbidities, and is especially important with respect to communities of color who are disproportionately affected and suffer disparate outcomes from both HIV and SARs-CoV-2 infections.

Our positions are supported by the June 2020 FDA’s [Development and Licensure of Vaccines to Prevent COVID-19](#) Guidance for Industry which provides in pertinent part on page 11:

“Evaluation and vaccine safety and efficacy in late phase clinical development in adults should include adequate representation of elderly individuals and individuals with medical comorbidities.”

Enrollment in COVID-19 clinical trials, including vaccine trials must reflect the populations who have been most impacted by COVID-19, especially communities of color who are experiencing both disproportionate SARs-CoV-2 infections and disparate COVID-19 outcomes. [Polling indicates](#) that just 50% of Americans plan to get a COVID-19 vaccine when one becomes available, with just 25% of Black/African Americans and 37% of Latinx reporting that they plan to get a vaccine when available. To build trust and avoid policies that can compromise trials, such as the exclusion of people with HIV or other populations, community representatives must be involved in COVID-19 clinical trials design and development from the onset, not only engaged to further study recruitment.

All COVID-19 clinical trial sponsors must be held to this critical standard if they are to be successful in delivering effective treatment and prevention interventions expeditiously. The NIH is in a perfect position to explain to sponsors that we will need community trust in order to accrue trials and develop products the US population will not be afraid to actually take after FDA approval. NIAID has had an excellent record of drug development community engagement success which has benefitted all HIV stakeholders, and which has been translated to models for other diseases.

The HIV community was promised that there would be community representation in all aspects of COVID-19 clinical trials development. But all we see is procrastination which now appears to be purposeful. Many of us surmised that community involvement would occur via the already established NIAID Community Advisory Board (CAB) networks which are already in place and well-established with seasoned committed members with many years of dedicated service. There is no good reason why these CABs cannot be utilized and provided adequate funding until the NIH can constitute COVID-19 CABs.

Unfortunately, we have learned that you intend to create community engagement structures for COVID-19 and all other diseases. What we do not need here is another level of underfunded bureaucracy which will take who knows how long to implement. This is an urgent matter, just as urgent as every other aspect of COVID-19 drug treatment and prevention intervention development. We need COVID-19 community engagement NOW! If there had been community participation in the development of the mRNA-1273 vaccine trial, we seriously doubt that we would find ourselves in this untenable predicament.

Further, even though there have been a number of nominations sent to the COVID-19 Guidelines Panel, to date all candidates have been rejected. We are also hearing that Moderna and Operation Warp Speed members are adverse to any community involvement. This unwise pattern of conduct reeks of community exclusions and promotes distrust which will adversely affect COVID-19 recruitment goals and intervention acceptance after FDA approval. This is particularly true in the vaccine arena.

While we understand the unprecedented urgency of the COVID-19 global health crisis like and appreciate the necessity of advancing COVID-19 clinical trials without delay, the effectiveness of COVID-19 treatment and prevention interventions will be significantly diminished if they are not widely accepted by individuals in the U.S. and globally, and studied in diverse populations, especially communities of color who need them the most. There are approximately 38 million people living with HIV globally, 25 million of whom are on antiretroviral therapy. They have an important role to play in clinical trials. We must understand their response to COVID-19 treatment and prevention interventions. To exclude people with HIV from the first US Phase 3 COVID-19 trial with an n of 30,000 people based on no scientific justification is unconscionable.

We again urge you to intercede with Moderna to ensure that people with HIV are not excluded from the current their Phase 3 mRNA-1273 trial, and assure us that you do will do everything in your power to ensure that no future COVID-19 vaccine trials or other treatment or prevention trials exclude people

with HIV. Please also share your plan to ensure communities of color and people with HIV are enrolled US clinical trials and involved in community engagement regarding not only recruitment efforts, but also in trust promoting clinical trial design issues and protocol development.

Thank you for your essential work and your commitment to the HIV and SARS-CoV-2 pandemics. Your time and efforts are greatly appreciated. We look forward to your prompt response.

Yours truly,

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