Dr. Francis Collins, National Institutes of Health

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Bethesda, MD 20892

Challenge Trials for COVID-19

Dear Dr. Collins,

The COVID-19 pandemic must be fought urgently on many fronts, but it is hard to picture robust economic and social recoveries in the absence of a vaccine. We are writing to underscore the vast importance of human challenge trials as a method to help develop vaccines.

In April, thirty-five members of the US House of Representatives called upon U.S. regulators to consider allowing volunteers to be infected with the pandemic coronavirus to speed vaccine testing—in so-called human challenge or controlled infection trials. In addition, over a hundred vaccine candidates are already under development around the world, at least ten of which have moved into the clinical trial phase. In May, the World Health Organization published guidance supporting trials of that form, if done ethically, and in June published a draft laying out a practical roadmap for their implementation.

The undersigned urge the U.S. government (including, but not limited to the Coronavirus Task Force, the Department of Health and Human Services, the Food and Drug Administration, Centers for Disease Control and Prevention, National Institutes of Health, and Congress), its allies, international funders, and world bodies (e.g. the World Health Organization), to undertake immediate preparations for human challenge trials, including supporting safe and reliable production of the virus and any biocontainment facilities necessary to house participants.

Background

The rationale for human challenge trials is that they can greatly accelerate the development of a COVID-19 vaccine.

Human challenge trials can provide information much faster than conventional efficacy trials, which take months longer. In such trials, volunteers still receive the vaccine candidate or a control. Instead of resuming life as usual and waiting to "catch" a virus, volunteers are deliberately exposed to the pathogen under controlled conditions. Beyond being faster than conventional trials, a challenge test is likelier to conclude with interpretable results, e.g. should the presence of virus around the study site begin to fade over time.

If challenge trials can safely and effectively speed the vaccine development process, there is a formidable presumption in favor of their use, which would require a very compelling ethical justification to overcome.

Principles for an Effective COVID-19 Human Challenge Trial

Human research demands caution and oversight. Crucial protections must be extended to protect the health and autonomy rights of volunteers. Guidance from the World Health Organization clarifies that human challenge trials are ethical when they meet certain criteria. The following are some protections that should clearly be in place.

- Trial participants should be relatively young and in good health. The mortality risk of the coronavirus to 20-29 year-olds, healthy and unhealthy, is similar to that of living kidney donors , a relatively common procedure, similarly justified by the donor's informed consent and the benefits to society. Excluding participants with preexisting conditions would lower the risk significantly.
- It is crucial that all trial participants be provided the highest quality medical care with frequent monitoring. A significant percentage of the population will likely become infected and their access to medical care may be limited. As a result, the guarantee of excellent medical care in the study means that infection would be safer in the controlled, medically supervised, and isolated conditions of a challenge trial.
- Ethical and scientific review must be of the highest quality. In the U.S., that would mean not only the usual FDA and IRB review but a vigorous public discussion and perhaps even an additional, independent ethics and science taskforce representing, among others, challenge volunteers.
- The autonomy of the volunteers is of paramount concern. This means that the informed consent process must be robust (e.g. no children, no prisoners, multiple tests of comprehension). It also means that the wish of informed volunteers to participate in the trial ought to be given substantial weight. Providing some input over trial development and procedure to those interested in becoming volunteers (e.g. in the design of isolation conditions) could both enhance their agency and improve study design. Decades of psychological research on highly altruistic behaviors has demonstrated that a large, and likely growing, fraction of the general population is willing to undergo meaningful risks to benefit others due to genuinely altruistic motivation rather than insensitivity to risk, psychopathology, or other ethically concerning motives.

If done properly, live Coronavirus human challenge trials can be an important way to accelerate vaccine development and, ideally, to save the lives of millions around the world as well as help rescue global economies. We strongly recommend that production of the unattenuated virus begin immediately consistent with good manufacturing practices for potential use in trials that balance risks and benefits and respect the safety and autonomy of volunteers. It is also vitally important that there is both full transparency on the vaccine development and trial process and a diverse group of trial participants necessary to provide a broadly effective and universally available vaccine. We appeal to the government and foundation funders around the world to support this effort.

Sincerely,

Initial Signatories in italics. Institutional affiliations for identification purposes only:

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