

# The ethics of human challenge trials

December 9 2020

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The first human challenge trial to test COVID-19 treatments and vaccines is set to begin in January in the United Kingdom. These trials, in which healthy volunteers are infected with the virus after being given different vaccines under development, have sparked ethical debates around the benefits of developing a vaccine quickly and the risks of directly exposing people to coronavirus.

"I looked for a compelling ethical objection to [challenge](#) trials for COVID-19 vaccines but found none—assuming they have the huge benefits and low risks that have been claimed," said Daniel Hausman, a research professor at Rutgers Center for Population-Level Bioethics. He discussed the findings of his recently published paper in the *Journal of Medicine & Philosophy* examining ethical issues of challenge trials.

## **What are the benefits and risks of challenge trials?**

Human challenge trials involve giving healthy volunteers a candidate [vaccine](#) or a placebo and deliberately exposing them to coronavirus in order to test the effectiveness of the therapy.

Since researchers don't have to wait for participants to be exposed to the virus naturally, some suggest challenge trials will save considerable time and thousands of lives in the midst of the pandemic. By selecting only a small number of young and healthy volunteers, the risk that any would be hospitalized would be very low, and the risk of permanent injury or death lower still.

One might think that the possibility that challenge trials would save thousands of lives could easily justify subjecting well-informed volunteers to these risks. However, some ethicists and some members of the public still have qualms. It is these that I try to understand and respond to.

## **What ethical questions arise in challenge trials?**

One argument rests on the general principle that researchers ought not to expose [healthy volunteers](#) to more than minimal risks, unless the research has therapeutic value for the volunteers. Since the participants in the control arm of a human challenge trial are exposed to the virus

without any vaccination, these studies violate the general principle and are ethically unacceptable.

In my paper, I respond that the principle is mistaken. Taken seriously, it would rule out most research. While there must be an expected benefit to justify imposing risks on participants, the benefit does not need to be for participants themselves.

Another argument rests on the principle that it is never morally permissible to intentionally harm innocent people. Human challenge trials would violate that principle, but so do other practices that are unobjectionable, such as kidney transplants from live donors, which intentionally impose harm on the donors. Once again, the supposed principle is mistaken.

Finally, there are doubts about how much risk experiments can impose on the whole group of participants, even if the risk to each individual is small. That's a judgment call, but given the potential benefits from human challenge trials, I would call it in their favor.

## **Are the ethical questions around challenge trials compelling?**

If volunteers are harmed or killed, it risks potentially undermining the public's confidence in medical research and professionals, and some oppose challenge trials because of this. This is a serious concern, but the potential benefits seem to justify these [risks](#).

After examining each of these arguments, the [ethical questions](#) around potential harms are not compelling when considering the massive benefits challenge [trials](#) are expected to provide in the COVID-19 pandemic.

**More information:** Daniel M Hausman, Challenge Trials: What Are the Ethical Problems?, *The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine* (2020). [DOI: 10.1093/jmp/jhaa028](https://doi.org/10.1093/jmp/jhaa028)

Provided by Rutgers University

Citation: The ethics of human challenge trials (2020, December 9) retrieved 24 April 2024 from <https://medicalxpress.com/news/2020-12-ethics-human-trials.html>

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