

If healthy people are purposefully infected with COVID-19 for the sake of science, they should be paid

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Multidisciplinary team of international experts suggests participants should receive a "substantial" amount, be paid ethically. Credit: Taylor & Francis The American Journal of Bioethics

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Healthy people volunteering to be infected with SARS-CoV-2, in order to help scientists better understand how to tackle the virus, should receive [payment](#)—if it is determined that these studies are otherwise ethical to proceed.

Those are the findings of a new peer-reviewed study published in the *American Journal of Bioethics*, which has assessed the ethics of paying participants to take part in so-called 'Human Infection Challenge Studies' (HICS).

Over the past few months there has been vast media coverage and discussion about the first COVID-19 HICS in the world, planned to begin in the UK later this year. This type of study can be particularly valuable for testing vaccines and can speed up the development of new vaccines.

Using HICS for a disease that can be fatal and currently lacks a cure is ethically controversial. Part of that controversy has to do with whether participants should be paid for such a risky endeavor and how payment might affect their consent.

Among the advocates of pursuing COVID-19 challenge trials is the organization, 1Day Sooner.

1Day Sooner sponsored the report on which the new study is based, seeking an independent assessment of whether and how much people should get paid to take part in challenge trials.

The international research team from the UK, US, and Canada does not necessarily endorse the use of HICS for COVID-19. But if HICS

proceed, their findings reflect that not only should participants be paid, but their payment should be "substantial".

The research team—including experts in bioethics, economics, science, medicine, and law, as well as two individuals expressing interest in participating in SARS-CoV-2 HICS—created a framework for scientists to follow in order to ethically assess payments for people taking part in HICS. They also looked at payment in similar studies, but noted the difficulty of finding out this information.

"Our work was spurred by concerns that payment for SARS-CoV-2 HICS might require a novel [ethical framework](#), which we ultimately determined to be unfounded," states lead author Holly Fernandez Lynch, John Russell Dickson, MD Presidential Assistant Professor of Medical Ethics at the Perelman School of Medicine, University of Pennsylvania.

"Payment for HICS participation should be treated like payment in other [clinical studies](#) involving healthy participants," she says.

"High offers of payment are sometimes met with scrutiny and concern, but it can be ethically appropriate to offer substantial payment for research participation and we have to consider that low payment also raises significant ethical concerns."

Professor Fernandez Lynch, who is a lawyer and bioethics expert, adds: "SARS-CoV-2 HICS should not be allowed to proceed in any setting in which there have not been adequate provisions made for compensating research-related harms, as well as other efforts to minimize risk and promote social value.

"Our hope going forward is that our analysis will serve both to ease concerns about payment in these studies, should they proceed, and to advance the broader project of ensuring ethical payment to participants

in all clinical research."

The framework the team has developed is split into two-parts. The first focuses on three main motives for payment: 'reimbursement' (for out-of-pocket expenses), 'compensation' (which includes payment for time, burden, inconvenience of isolating, etc.), and 'incentive' (to broaden the range of individuals willing to consider participation). The second part considers appropriate compensation in the event any harm materializes—ranging from injury to death.

In developing the framework, the team paid special attention to public trust, acknowledging that "research payments could affect [public trust](#) in several ways". Ultimately, they conclude that "the best way to promote trust in HICS is by helping the public understand why this design can be both scientifically important and ethically acceptable".

"HICS can proceed only when strict research and ethical standards are satisfied," says co-author Thomas Darton, from the Department of Infection, Immunity and Cardiovascular Disease at The University of Sheffield.

Dr. Darton is a HICS researcher, although he does not work with the SARS-CoV-2 virus.

He states: "If the risks associated with these studies are unreasonable in relation to their potential benefits, payment for participation cannot help achieve ethical acceptability. But if the research is otherwise ethical, it doesn't become unethical simply because payment is offered."

Another factor the team considered is whether COVID-19 HICS would be "uniquely risky" and how that should influence payment levels. Ultimately, they concluded that "the ethical concerns about payment for these studies are the same as those for payment in all clinical research".

"Although certainly relevant to considerations regarding the ethical acceptability of HICS, including the importance of planning for research-related harm, heightened risks do not support adopting a novel framework for HICS payment as compared to other types of research," adds co-author Emily Largent, the Emanuel and Robert Hart Assistant Professor of Medical Ethics at the Perelman School of Medicine, University of Pennsylvania.

Limitations of the project include the team's perspectives being "limited to the Global North". They state, therefore, that additional considerations may be relevant when research is conducted elsewhere. The team also declined to identify a payment amount or even a range that would be appropriate for HICS or SARS-CoV-2 HICS. "Stakeholders must take the final step between conceptual guidance and actual payment offers on their own," the paper concludes. "This means that there may be several different payment offers that could be justified, but the framework can help determine which offers are ethically appropriate," says Professor Fernandez Lynch.

More information: *American Journal of Bioethics*, [DOI: 10.1080/15265161.2020.1854368](https://doi.org/10.1080/15265161.2020.1854368)

Provided by Taylor & Francis

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