

# COVID-19 vaccine development: New guidelines for ethical approach to infecting trial volunteers

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Dr. Adair Richards, of the University of Warwick's Department of Chemistry.  
Credit: Dr. Adair Richards

Allowing consenting volunteers to be deliberately infected with COVID-19 for the purposes of developing a vaccine could be done

ethically and potentially speed up its development, a University of Warwick researcher has argued in new research.

Dr. Adair Richards at the University of Warwick has developed a set of ethical guidelines to guide researchers on an ethical approach to deliberately infecting volunteers who have been given a [vaccine candidate](#) with COVID-19.

He argues that this may significantly speed up the process of vaccine development and potentially save many lives. The work has been externally double-blind peer-reviewed and is published today in the *Journal of Medical Ethics*.

Dr. Adair Richards is an Associate Professor in the University of Warwick's Department of Chemistry and leads on research ethics training for postgraduate researchers in science and medicine. He said: "Currently there are several vaccine candidates that are undergoing human safety testing, but to find out whether they work we need to discover what happens when a vaccinated person is exposed to COVID-19. With new infections dropping in the countries where research is taking place, it may be a long time before many of the volunteers in these experiments naturally come into contact with the disease.

"Deliberately infecting volunteers with a disease as dangerous as COVID-19 has previously been considered to be unethical by the research community. However I believe that the current global situation is so different to those previously faced, that it is ethical in this case.

"In other areas of life it is not unusual for society to allow individuals to do things that put them at [personal risk](#), such as to be a fire fighter or a health professional treating COVID-19 patients. Speeding up vaccine development even by a few weeks or months could result in saving many

lives."

The research analyses each of the common arguments against these types of experiments: the risk of harm to volunteers; the risk of no useable vaccine; the validity of a volunteer's informed consent; the reputational risk to research; and that this could be a slippery slope to increasingly unethical research.

Dr. Richards demonstrates that these arguments can be overcome and in fact we do not need to lower our [ethical standards](#) to permit these types of experiment, and that it is possible to put sufficient ethical safeguards in place.

The article provides guidance for regulators and researchers and poses three key questions for those planning vaccine development studies:

- Has reasonable care been taken to maximise the potential benefits of the proposed study and minimise the risks of harm to participants?
- Is the informed consent process sufficiently robust?
- What do we need to do now to amend our processes to speed up the consideration and approval processes for proposed COVID-19 vaccine candidate phase II and phase III trials?

Dr. Richards adds: "My research shows that it is incorrect to rule out human challenge experiments as unethical in relation to COVID-19 vaccine development. I argue that you can apply the same standards of ethics, but that they lead us now to a different conclusion because the facts are different.

"Very large numbers of people globally are affected both directly and indirectly from COVID-19, and the saving of a few weeks or months of time in [vaccine](#) development can be expected to result in saving a large

number of lives. There are also good ways to minimise the risk of harm to volunteers, and it is ethical, and I argue, admirable to allow a [volunteer](#) to choose to take a personal health risk to help serve a greater benefit to humanity."

**More information:** Ethical Guidelines for Deliberately Infecting Volunteers with COVID-19, *Journal of Medical Ethics* (2020). [DOI: 10.1136/medethics-2020-106322](#)

Provided by University of Warwick

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