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RESEARCH ARTICLE

Never Waste a Good Crisis[1]: COVID-19 and Research Ethics

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Abstract

The public health crisis caused by the COVID-19 pandemic led to a rapid surge in activity in biomedical and social science. The pandemic created a need for new scientific knowledge specifically related to the new, emerging infectious agent and it quickly showed huge gaps in knowledge in relation to social and policy responses to pandemics. Governments all over the world accepted the COVID-19 pandemic as a significant public health crisis and went into crisis mode in order to end the crisis and mitigate its impacts. One area in which rapid policy changes occurred was in relation to research ethics. Research ethics systems and guidelines were changed in many countries. The COVID-19 crisis also led to a flurry of philosophical and bioethical work arguing that traditional research ethics rules and principles should be suspended, rethought, or abolished. This essay will analyze whether a public health crisis justifies changing research ethics principles and policies and, if so, what the scope of justified changes is.

Keywords: challenge study; COVID-19; crisis; research ethics; research risk; social value; state of exception

Introduction

The public health crisis caused by the COVID-19 pandemic led to a rapid surge in activity in biomedical and social science. The pandemic created a need for new scientific knowledge specifically related to the new, emerging infectious agent and it quickly showed huge gaps in knowledge in relation to social and

[1] This is a paraphrase of a saying commonly attributed to Saul Alinsky as: "Never let a good crisis go to waste." While Alinsky writes about this issue in his *Rules for Radicals*, he did not use those exact words. Saul Alinsky, *Rules for Radicals* (New York: Random House, 1971), p. 1.

policy responses to viral pandemics in general. The social and economic impact of the pandemic in the affluent countries of the global North also created the conditions that at the same time enabled and forced governments to make financial resources available to support research. Alongside the financial resources, research policies were also changed in order to facilitate rapid and effective COVID-19-related research. To put it differently, governments all over the world accepted the COVID-19 pandemic as a significant public health crisis and went into crisis mode in order to end the crisis and mitigate its impacts.

One area in which rapid policy changes occurred was in relation to research ethics. Research ethics systems and guidelines were changed in many countries. The COVID-19 crisis also led to a flurry of philosophical and bioethical work arguing that traditional research ethics rules and principles should be suspended, rethought, or abolished. This essay will analyze whether a public health crisis justifies changing research ethics processes, policies, and principles and, if so, what the scope of justified changes is.

The essay will first briefly describe some of the changes in research ethics that occurred worldwide during the COVID-19 pandemic as well as some of the further changes that philosophers argued for. It will outline a schematic argument underlying many of these specific proposals.

The essay then provides an analysis of the two main components of the schematic argument: (1) premises concerning the (large) social value of COVID-19 research and (2) premises concerning the negative effects of research ethics on COVID-19 research. It will be shown that both of these components of the argument are problematic.

Next, this essay considers two aspects of power in relation to a crisis: the definitional power to declare the beginning of a crisis and the substantive power to act that follows from the crisis being a "state of exception." This section of the essay will draw on the extant analyses of the power of the World Health Organization (WHO) to declare a "Public Health Emergency of International Concern" and the work of Giorgio Agamben on the state of exception.[2]

Background

During the COVID-19 pandemic many countries made very similar changes to research ethics and to approval processes for pharmaceutical products and medical devices.[3] In relation to processing applications in the research ethics

[2] Clare Wenham et al., "Problems with Traffic Light Approaches to Public Health Emergencies of International Concern," *The Lancet* 397, no. 10287 (2021): 1856–58. David P. Fidler, "To Declare or Not to Declare: The Controversy over Declaring a Public Health Emergency of International Concern for the Ebola Outbreak in the Democratic Republic of the Congo," *Asian Journal Of WTO & International Health Law and Policy* 14, no. 2 (2019): 287–331. Fiona Godlee, "Conflicts of Interest and Pandemic Flu," *British Medical Journal* 340 (2010), https://doi.org/10.1136/bmj.c2947.

[3] Meghna Ann Arunachalam, Aarti Halwai, and Cynthia Arunachalam, "National Guidelines for Ethics Committees Reviewing Biomedical & Health Research during COVID-19 Pandemic: An Analysis," *Indian Journal of Medical Ethics* 6, no. 1 (2021): 1–12.

and regulatory systems there was a strong focus on increasing speed and efficiency, so that COVID-19-related projects and products could quickly be assessed and approved. This involved changes, including (1) general streamlining of approval processes, (2) relaxation of some process requirements, (3) COVID-19-specific fast tracks,[4] and (4) a pause in the approval of research not related to COVID-19 to make space for COVID-19-related research. These were changes to the research ethics process, but not to the principles and rules by which research ethics bodies made their decisions.

Many countries also relaxed some substantive research ethics rules. These changes ranged from relatively trivial changes such as broadening the criteria for accepting information given orally and oral consent in clinical research to more substantial changes such as relaxing the rules for access without consent to health and other data.[5]

Some scholars in the philosophical and bioethical literature argued that the COVID-19 pandemic justified further and more radical changes to research ethics rules and principles than those that were implemented in most jurisdictions. The fundamental structure of these arguments is remarkably similar across different authors and can be summarized in the following schematic argument:

(P1) The COVID-19 pandemic is a major public health crisis with very large negative consequences.

(P2) From P1: Any medical intervention that can reduce the net negative consequences of the COVID-19 pandemic has very large social value.

(P3) From P1 and P2: Research necessary to show that a medical intervention can reduce the net negative consequences of the COVID-19 pandemic has very large social value.

(P4) From P1 and P2: Research necessary to show that a medical intervention can reduce the net negative consequences of the COVID-19 pandemic is urgent.

(P5) X is a medical intervention that can reduce the net negative consequences of the COVID-19 pandemic.

[4] "Fast Track Review Guidance for COVID-19 Studies," *Health Research Authority*, January 6, 2022, https://www.hra.nhs.uk/covid-19-research/fast-track-review-guidance-covid-19-studies/; Silvia Tusino and Maria Furfaro, "Rethinking the Role of Research Ethics Committees in the Light of Regulation (EU) No 536/2014 on Clinical Trials and the COVID-19 Pandemic," *British Journal of Clinical Pharmacology* 88, no. 1 (2022): 40–46.

[5] World Health Organization, "Joint Statement on Data Protection and Privacy in the COVID-19 Response," November 19, 2020, https://www.who.int/news/item/19-11-2020-joint-statement-on-data-protection-and-privacy-in-the-covid-19-response; Angela Wood et al., "Linked Electronic Health Records for Research on a Nationwide Cohort of More Than 54 Million People in England: Data Resource," *British Medical Journal* 373 (2021), https://www.bmj.com/content/373/bmj.n826; Chris Stokel-Walker, "How Health Data Have Been Used during COVID-19, and Whether the Changes Are Here to Stay," *British Medical Journal* 372 (2021), https://www.bmj.com/content/372/bmj.n681.

(IC1) Interim Conclusion 1 from P1–P5: Research into X has large social value and is urgent.

(P6) Research ethics hinders research into X.

(P6*) Research ethics slows down research into X.

(P6**) Research ethics prohibits the most effective way of researching X.

(C) From IC1 and one or more of P6–P6**: Research ethics must be changed to allow X to be researched urgently and with the most effective methods.

Versions of this schematic argument provide the justification for many of the changes to research ethics proposed during the COVID-19 pandemic, although often with a number of the premises not fully stated. This is probably most fully stated in the academic literature arguing for the permissibility of COVID-19 human challenge studies[6] and by the advocacy group 1Day Sooner in relation to such studies.[7] In the argument the phrase "the COVID-19 pandemic" can without loss of validity be substituted in the premises in which it occurs by any other situation that can be described as "a major, urgent, public health crisis." This line of argument is often combined with an argument that the public health crisis created by COVID-19 is exceptional and that an exceptional crisis justifies exceptional measures.

Very similar arguments were made in relation to the methodological quality of research during the COVID-19 crisis where some argued for a relaxation of methodological standards in order to speed up research and get evidence faster. These arguments have been heavily criticized[8] and are outside the scope of this essay. It is, however, worth noting in passing that insofar as methodological exceptionalism was actually implemented, it led to a crisis in evidence production and an epidemic of retractions of preprints and published articles.[9]

[6] Linh Chi Nguyen et al., "Evaluating Use Cases for Human Challenge Trials in Accelerating SARS-CoV-2 Vaccine Development," *Clinical Infectious Diseases* 72, no. 4 (2021): 710–15; Nir Eyal, Marc Lipsitch, and Peter G. Smith, "Human Challenge Studies to Accelerate Coronavirus Vaccine Licensure," *The Journal of Infectious Diseases* 221, no. 11 (2020): 1752–56.

[7] "Ending Infectious Diseases, One Day Sooner," https://www.1daysooner.org/.

[8] Alex John London and Jonathan Kimmelman, "Against Pandemic Research Exceptionalism," *Science* 368, no. 6490 (2020): 476–77; Angus Dawson, "Pandemic Vaccine Trials: Expedite, but Don't Rush," *Research Ethics* 16, nos. 3–4 (2020): 1–12.

[9] Priscila Rubbo et al., "'Research Exceptionalism' in the COVID-19 Pandemic: An Analysis of Scientific Retractions in Scopus," *Ethics & Behavior* 33, no. 5 (2022): 339–56; Vignan Yogendrakumar et al., "Many Trials of Hydroxychloroquine for SARS-CoV-2 Were Redundant and Potentially Unethical: An Analysis of the NIH Clinical Trials Registry," *Journal of Clinical Epidemiology* 143 (2022): 73–80; Gideon Meyerowitz-Katz et al., "Unethical Studies of Ivermectin for COVID-19," *British Medical Journal* 377 (2022), https://www.bmj.com/content/377/bmj.o917.

Changes to research ethics during the COVID-19 pandemic

This type of argument has been used to argue for more specific changes to research ethics, ranging from the kind of process changes implemented in many jurisdictions to significant substantive changes to research ethics principles. It is impossible to list all of the suggested substantive changes, but they include conscription to vaccine research,[10] allowing research that puts research participants at significant risk of injury or death,[11] allowing researchers to pay participants to take on significant research risk,[12] and so on. There are specific counterarguments against many of the proposals for changes in research ethics principles, such as those in the now extensive literature on COVID-19 human challenge studies.[13] In this essay we are, however, focusing on the underlying, common, in-principle argument outlined above.

There are many other examples of suggestions for changes in research ethics that some claim are justified by the COVID-19 pandemic. The apogee of this line of argument was probably reached when some claimed in all sincerity that COVID-19 provided an urgent reason for the release and use of data and results from the infamous medical experiments conducted by Unit 731 of the Imperial Japanese army in Manchuria prior to and during World War II.[14] The relevant microbiological research performed by Unit 731 was on possible *bacterial* biological weapons and (obviously) done with methods available in the 1930s and early 1940s and on the basis of biological knowledge that was available at that time. It is not logically impossible that the research could be of value in relation to COVID-19, but it is exceedingly unlikely. COVID-19 is a *viral* disease and interacts with the body in fundamentally different ways than bacterial diseases do. Whatever knowledge Unit 731 developed about bacterial diseases would be based on what today would be seen as exceedingly simple, obsolete, or false biological theories. There are good reasons for demanding the release of all Unit 731 data from Japanese, American, and Russian archives to enable a full understanding of the atrocities committed, but the COVID-19 pandemic adds nothing to these reasons.

The basic principles of research ethics and the general structure of the research ethics system are both the results of prior crisis moments in medical

[10] Julian Savulescu, "Is It Right to Cut Corners in the Search for a Coronavirus Cure?" *The Guardian*, March 25, 2020, https://www.theguardian.com/commentisfree/2020/mar/25/search-coronavirus-cure-vaccine-pandemic.

[11] Richard Yetter Chappell and Peter Singer, "Pandemic Ethics: The Case for Risky Research," *Research Ethics* 16, nos. 3–4 (2020): 1–8.

[12] Holly Fernandez Lynch et al., "Promoting Ethical Payment in Human Infection Challenge Studies," *The American Journal of Bioethics* 21, no. 3 (2021): 11–31.

[13] Søren Holm, "Controlled Human Infection with SARS-CoV-2 to Study COVID-19 Vaccines and Treatments: Bioethics in Utopia," *Journal of Medical Ethics* 46, no. 9 (2020): 569–73; Søren Holm, "Incentive Payments and Research Related Risks—No Reason to Change," *The American Journal of Bioethics* 21, no. 3 (2021): 43–45; Jan Helge Solbakk et al., "Back to WHAT? The Role of Research Ethics in Pandemic Times," *Medicine, Health Care, and Philosophy* 24 (2021): 3–20.

[14] Zhaohui Su et al., "The Promise and Perils of Unit 731 Data to Advance COVID-19 Research," *British Medical Journal: Global Health* 6, no. 5 (2021): https://gh.bmj.com/content/6/5/e004772.

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research.[15] The primacy of the interests of the participant, the requirement for consent, and the right to withdraw from research as stated in the Nuremberg Code was a direct response to the research atrocities perpetrated by German and other researchers in the concentration camps during World War II.[16] World War II and the Cold War that followed it were seen as existential crises in many democratic countries; this perception of crisis was used as an argument for performing potentially harmful biomedical research without consent and sometimes without even the knowledge of the research participants.[17] When the Nuremberg Code was "rediscovered" in the 1960s, it became evident that the principled protection it put in place for research participants was relevant not only to Nazi doctors, but also to much research taking place in the U.S. and the U.K.

In a similar way, the general structure of the research ethics system as a regulatory system providing "event licenses" to researchers to conduct a specific project was a response to the increasing realization in the late 1960s and early 1970s that medical research was still taking place in ways that were deeply unethical and, in many cases, contravened the Nuremberg Code. It was primarily because of the spotlight put on highly problematic medical research by doctors such as Henry Beecher[18] and Maurice Pappworth[19] and through the shock of public revelations of the Tuskegee study that we ended up with a regulatory system based on the prior approval of research protocols by an independent committee with lay representation.[20] This particular crisis showed convincingly that research ethics could not be left to researchers and health-care professionals. Research ethics is thus born out of crises and as a response to what researchers are seemingly willing to do and policymakers seemingly willing to allow during perceived crises.[21] Over time, research ethics has been codified in a number of international normative documents with varying legal status.[22]

[15] Solbakk et al., "Back to WHAT?"

[16] George J. Annas and Michael A. Grodin, "Medicine and Human Rights: Reflections on the Fiftieth Anniversary of the Doctors' Trial," *Health and Human Rights* 2, no. 1 (1996): 6–21.

[17] Robert Baker, *Making Modern Medical Ethics: How African Americans, Anti-Nazis, Bureaucrats, Feminists, Veterans, and Whistleblowing Moralists Created Bioethics* (Cambridge, MA: The MIT Press, 2024); Advisory Committee on Human Radiation Experiments, *The Human Radiation Experiments* (New York: Oxford University Press, 1996).

[18] Henry K. Beecher, "Ethics and Clinical Research," *The New England Journal of Medicine* 274, no. 24 (1966): 1354–60.

[19] Maurice H. Pappworth, *Human Guinea Pigs: Experimentation on Man* (London: Routledge, 1967).

[20] Søren Holm, "*Belmont* in Europe: A Mostly Indirect Influence," *Perspectives in Biology and Medicine* 63, no. 2 (2020): 262–76.

[21] For some of the many other examples of problematic medical research conducted in crises situations, see Jing Bao Nie et al., eds., *Japan's Wartime Medical Atrocities: Comparative Inquiries in Science, History, and Ethics* (London: Routledge, 2010); Lisa M. Rasmussen, ed., *Human Guinea Pigs, by Kenneth Mellanby: A Reprint with Commentaries* (Cham: Springer, 2020); Sydney A. Halpern, *Dangerous Medicine: The Story behind Human Experiments with Hepatitis* (New Haven, CT: Yale University Press, 2021).

[22] Including the Nuremberg Code; the World Medical Association Declaration of Helsinki; the Council for International Organizations of Medical Sciences Guidelines; the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine and its

Justifying research ethics exceptionalism: Social value

Is the schematic argument outlined above valid and sound, leading to a true conclusion that research ethics must be changed in a major public health crisis if there is at least one possible intervention X that makes P5 true and one or more of P6–P6** also hold?

The first observation to make is that P5 as stated so far is ambiguous between "can definitely" and "can potentially." In many cases, we do not yet know whether a particular intervention X is effective or not and the main point of researching X is to generate evidence about the effectiveness of X. So, in most cases, P5 should be stated as P5*: "X is a medical intervention that can *potentially* reduce the net negative consequences of the COVID-19 pandemic." There may be cases where we already know that X is effective and where the research needed is therefore about, for instance, how X can best be deployed. In those cases, P5 will hold in its original form. It is, however, much less likely that P6 or P6** will be true if an intervention is already known to be effective. Thus, when P5 is true and can be read as "X … can *definitely* reduce," then the relevant P6 premise will almost always be P6* and a procedural rather than a substantive change to research ethics would need justification.

In cases where P5* is the relevant premise because it is possible that X is effective, a question arises about the importance of the ex ante likelihood of X being effective to the validity of the argument from P1–P5* to IC1. Is it true that "Research into X has large social value and is urgent," if the ex ante likelihood of X being effective is small? Seen in isolation and focusing on only one intervention at a time, the answer to this question depends on whether or not you believe that von Neumann-Morgenstern expected utility theory[23] as a model for rational choice holds in situations where an outcome has a small likelihood but a high positive utility if it happens. To put it slightly more contentiously, it depends on whether or not you believe that the consequentialist is pulling a "trick" when claiming that the possibility that X could save millions of lives is a convincing and dispositive reason to making the pursuit of X the overriding goal, even if the ex ante likelihood is low of X actually saving millions of lives. In an article arguing for the acceptability of human challenge studies and a range of other controversial COVID-19 interventions, Richard Chappell presents the consequentialist argument with admirable clarity in relation to the induction of early targeted immunity by deliberate viral inoculation, "variolation" of healthy volunteers. (He claims, somewhat unconvincingly, elsewhere in the article that this type of argument is not consequentialist.) Chappell argues:

> Depending upon the results of early research into variolation, *it is entirely possible* that such low-dose exposure could even be in the medical interests of the volunteers, by protecting them against the greater risk of an

protocols; and the United Nations Educational, Scientific, and Cultural Organization Universal Declaration on Bioethics and Human Rights.

[23] See John von Neumann and Oskar Morgenstern, *Theory of Games and Economic Behavior: 60th Anniversary Commemorative Edition* (Princeton, NJ: Princeton University Press, 2007).

> accidental high-dose exposure. But even if not, it could easily be in the interests of society as a whole, and it would thus be worth compensating the participants in order to make it in their overall interest to provide this social value... . *This is obviously all speculative.* But a central theme of this paper is that high uncertainty alone should not bias us against a pandemic policy proposal. The question is whether—taking the full range of possibilities into account, weighted by their probability—the *expected value* of the proposal should be judged positive or negative on net. This is an empirical question, best answered by the relevant disciplinary experts. As a philosopher, I restrict myself to claiming that this is a question that ought to have been asked, and that we can see this because *it is prima facie plausible* that the correct expert judgment could well have been that the proposal in question had immensely positive expected value (however uncertain, or high-variance). Given that this was *a reasonable possibility*, we can see that to *not even ask the question* was to irresponsibly condemn to death many thousands *who very well might have been saved* by a more careful survey of the policy options, guided by expert cost–benefit analysis.[24]

In this quotation something admitted to be "obviously all speculative" becomes "entirely possible," "*prima facie* plausible," and then finally "a reasonable possibility," leading to the conclusion that decision-makers "irresponsibly condemn[ed] to death many thousands who very well might have been saved." However, because the whole argument is truly (as admitted explicitly by the author) "obviously all speculative," no one had condemned anyone to death. There are no people who "very well might have been saved," because the "very well might" only comes about through a series of unargued-for elisions from mere logical possibility to "reasonable possibility."

In this way, even a minimal likelihood of an intervention actually working can be converted to a large, expected benefit and an imperative to act, if the projected public health crisis is large enough. In many ways, this argumentative form is the reverse of the (in)famous slippery-slope argument. Instead of automatically sliding down the slope, we are effortlessly carried up the escalator by the promise of a pot of preventative or therapeutic gold in the future.[25]

The ex ante likelihood of whether an intervention is effective, though, is important in order to estimate the moral weight it creates; it will not do to say that in a public health crisis any likelihood is good enough. This can perhaps most easily be seen if we consider the fact that resources for research are not infinite. Resources are always limited, even during periods where governments open their purse strings because of a crisis. This is true of financial resources, such as

[24] Richard Yetter Chappell, "Pandemic Ethics and Status Quo Risk," *Public Health Ethics* 15, no. 1 (2022): 68–69, footnote removed, emphases added for the first, second, fourth, fifth, and seventh italicized phrases. See also, Robert Streiffer, David Killoren, and Richard Y. Chappell, "The Ethics of Deliberate Exposure to SARS-CoV-2 to Induce Immunity," *Journal of Applied Philosophy* 38, no. 3 (2021): 479–96.

[25] Søren Holm and Tuija Takala, "High Hopes and Automatic Escalators: A Critique of Some New Arguments in Bioethics," *Journal of Medical Ethics* 33, no. 1 (2007): 1–4.

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research funding, but it is also true of experienced researcher time, human participants for participant recruitment, and many other nonfinancial resources (some of which are nonfungible). This means that as soon as there is more than one intervention to research and there is competition for any of the necessary finite resources, a decision will have to be made about how to allocate the available resources. In that decision it will be crucial to estimate the likely effectiveness of each intervention as well as the likely magnitude of their effects. If we cannot estimate those two ex ante likelihoods for each of the interventions, we have no basis to make a rational choice or any choice at all about the allocation of research resources. Perhaps more importantly, in relation to the argument that in a public health crisis a minimal likelihood of effectiveness is sufficient to make an intervention something we should pursue in research, comparative analysis shows that this is not true unless pursuing the intervention that has ex ante minimal likelihood of effectiveness is costless.

We also need to note that predictions about the likelihood of research leading to effective interventions is notoriously uncertain. One example related to a still ongoing major epidemic illustrates this. It was conclusively shown in 1983–1984 that Human Immunodeficiency Virus (HIV) is the causative agent of Acquired Immunodeficiency Syndrome (AIDS) and it was predicted in 1984 that a vaccine would be available for testing in two to three years.[26] Such a vaccine would obviously have great social value and there is consensus that the AIDS crisis can only be completely overcome when an effective vaccine becomes available.[27] There has been significant investment and recent progress in HIV vaccine research over the years,[28] but almost forty years after the prediction of two to three years, we still do not have an effective vaccine.

Furthermore, because what drives the argument is the large social value of having effective responses to a public health crisis, we also need to consider the likelihood that an intervention X that has been shown to be effective is actually implemented as well as the speed of implementation or gap between evidence generation and implementation. In many cases, the knowledge that something works will not lead to its immediate implementation and, unless the intervention is actually implemented, the large social value is not generated.

In many cases, the main delaying step between X being hypothesized to be a possible intervention on the basis of some initial evidence and the implementation of X is not the research and evidence-generating step. The main delay often occurs in the steps after this, for example, scaling-up production if X is a pharmaceutical product or the practical introduction of X in the health-care

[26] José Esparza, "A Brief History of the Global Effort to Develop a Preventive HIV Vaccine," *Vaccine* 31, no. 35 (2013): 3502–18.

[27] Linda-Gail Bekker et al., "The Complex Challenges of HIV Vaccine Development Require Renewed and Expanded Global Commitment," *The Lancet* 395, no. 10221 (2020): 384–88.

[28] Punnee Pitisuttithum and Mary Anne Marovich, "Prophylactic HIV Vaccine: Vaccine Regimens in Clinical Trials and Potential Challenges," *Expert Review of Vaccines* 19, no. 2 (2020): 133–42; Tiza Ng'uni, Caroline Chasara, and Zaza M. Ndhlovu, "Major Scientific Hurdles in HIV Vaccine Development: Historical Perspective and Future Directions," *Frontiers in Immunology* 11 (2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7655734/.

system or other social systems. If the implementation of X is global, the main issue delaying implementation is almost always global inequality. The effects of global inequality were also evident during the COVID-19 pandemic. Citizens in high-income countries (HICs) were vaccinated long before citizens in low- and middle-income countries (LMICs); at the time of writing, there are still many countries where less than 70 percent of the eligible population has been vaccinated.[29] This may in some cases be due to vaccine hesitancy, but in others the main cause is unavailability. There is thus a great gap between the possible global social benefit of the development of a COVID-19 vaccine and the actual realized benefit. Such gaps between possible benefits of developing an effective intervention and actually realized benefits are completely predictable. For instance, even though an equitable global distribution of COVID-19 vaccines would have been highly preferable from the point of view of global justice and from the point of view of effective suppression of the pandemic,[30] it was completely predictable that the distribution would be highly inequitable and that vaccination in LMICs would be significantly delayed. The policy imperative for policymakers in HICs of getting their own populations vaccinated as quickly as possible was always likely to outweigh more abstract considerations of and commitments to global justice.[31]

In relation to estimating the social value created by research into a particular intervention there is also a potential issue of preemption that can occur, even if the intervention is quite likely to be effective. This issue is clearly illustrated by the development and deployment of COVID-19 vaccines, but it has also occurred in some other areas of COVID-19 therapeutics. Let us briefly look at the development and use of COVID-19 vaccines. As early as April 2020, 115 vaccines were in development following the publication in January 2020 of the genetic sequence of the original Wuhan strain of the SARS-CoV-2 virus.[32] At the time of writing, there are 379 COVID-19 vaccines listed as being in development on the WHO COVID-19 vaccine tracker,[33] 199 in preclinical development, and 180 in some phase of clinical development or already approved for use. Of the vaccines in clinical development most are injectable (as are the already marketed vaccines), but five are oral and eighteen are intranasal or inhaled, thereby offering potentially significant advantages in terms of mode of administration. According to the UNICEF COVID-19 market dashboard, fifty-eight vaccines have been approved for use in at least one country and eleven have achieved WHO

[29] UNICEF, "COVID-19 Market Dashboard," https://www.unicef.org/supply/covid-19-market-dashboard (last accessed July 7, 2023).

[30] Thomas J. Bollyky and Chad P. Bown, "The Tragedy of Vaccine Nationalism: Only Cooperation Can End the Pandemic," *Foreign Affairs* 99, no. 5 (2020): 96–109; Nicole Hassoun, "Against Vaccine Nationalism," *Journal of Medical Ethics* 47, no. 11 (2021): 773–74.

[31] Søren Holm, "Research Ethics in Exceptional Times: What Lessons Should We Learn from Covid-19?" in *Medical Research Ethics: Challenges in the 21st Century*, ed. Tomas Zima and David Weisstub (Cham: Springer International Publishing, 2023), 355–66.

[32] Tung Thanh Le et al., "The COVID-19 Vaccine Development Landscape," *Nature Reviews: Drug Discovery* 19, no. 5 (2020): 305–6.

[33] World Health Organization, "COVID-19 Vaccine Tracker and Landscape," March 30, 2023, https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines.

emergency listing, but only a limited number of these are in widespread use.[34] Of those, 17.8 billion doses have been purchased or ordered in the open market, but more than 15 billion of these come from only four developers: Pfizer/BioNTech, AstraZeneca, Moderna, and Novavax. Pfizer/BioNTech alone accounts for 7 billion doses. These numbers underestimate the importance of vaccines developed and used in China and Russia. They have been widely used in China and Russia, respectively, but have had little success in the market. The first approvals of the AstraZeneca and the Pfizer/BioNTech vaccines for clinical use were issued in December 2020.

This data allows us to consider the preemption and social value issues in more detail in relation to the schematic argument presented in the "Background" section above. At the start of the COVID-19 pandemic an effective COVID-19 vaccine would clearly substitute for the placeholder X in P5 ("X is a medical intervention that can reduce the net negative consequences of the COVID-19 pandemic") and any individual vaccine under development based on a reasonable vaccine technology would substitute for X in P5* ("X is a medical intervention that can *potentially* reduce the net negative consequences of the COVID-19 pandemic"). We might even be willing to replace "can potentially" with something like "is likely." However, reflecting on the data about COVID-19 vaccine development, we should probably rethink this last change. Of the 115 vaccines in development in April 2020, only a few completed development and, of those that completed development and were approved for clinical use, only a few have actually been produced and used at any significant volume (as shown above). Part of the reason for this is preemption. As soon as one effective vaccine is available the need for developing another objectively decreases, as does the incentive for both commercial and government actors to do so. The first approved vaccine (or vaccines, if more than one is approved at roughly the same time) is likely to be most used, even if better vaccines can be developed. The Pfizer/BioNTech vaccine is not perfect, because it does not provide 100 percent protection and the protection wanes over time, but it is good enough to diminish significantly the incentive to develop other vaccines, unless they offer something significantly different, for example, a different mode of administration, better logistics, or longer-lasting or lifelong protection. The research and development leading to the Pfizer/BioNTech vaccine clearly has generated very large social value ex post. This vaccine has saved many lives and prevented much suffering. But ex ante it was in competition for generating this social value with at least 100 other vaccines in development and most of those other vaccines never produced any social value apart from the knowledge generated through their ultimately unsuccessful development.

Partial preemption of social value can also occur between different types of interventions. If vaccines had not been developed, then the social value of effective social interventions and drug treatments would have increased manifold, as has until now been the case in relation to HIV/AIDS where promotion of condom use and safe-sex practices as well as effective anti-retrovirals for

[34] UNICEF, "COVID-19 Market Dashboard."

treatment and preexposure prophylaxis have delivered almost all of the social value following from HIV/AIDS research.

These considerations show that the link between (1) an intervention X being a possible effective intervention in relation to a particular public health crisis and (2) X and *a fortiori* research on X creating significant social value is much more complicated than it initially seems. Even in situations where X is proven by research to be effective, there is no guarantee that any social value will eventuate.

This skeptical argument concerning the predictability of a straightforward link between research, innovation, and social value for particular interventions can be criticized. A first possible criticism is that the argument ignores the possibility that a particular intervention can have a very long "tail," that is, that the intervention will continue to be used for a long time and therefore continue to accumulate net social value. A specific instance of this could be the Pfizer/BioNTech vaccine that will continue to be used for elderly and at-risk populations. The counterargument is that whereas it is true that some interventions will have long tails, this is no more predictable in relation to a particular intervention at the research stage than is whether that particular intervention will be effective and, if effective, will be widely used.

A second possible criticism is that it is problematic to look at specific interventions in isolation; the real connection between interventions, research, and social value is rather at the level of classes of interventions. A specific instance of this would be to move the focus from individual vaccines to classes of vaccine technologies. The mRNA technology that is the basis for both the Pfizer/BioNTech and the Moderna vaccines can, for instance, be used to develop vaccines for other infectious diseases and potentially also for vaccines that protect against various forms of cancer. The counterargument is again that whereas it is true that some new vaccine technologies can ex post be identified as having wider use and thereby significant social value, many novel vaccine technologies were researched and it was ex ante unpredictable which of these would be effective and produce large social value as technologies.

Justifying research ethics exceptionalism: Research ethics is an obstacle to research

The other important part of the schematic argument for changes in research ethics is represented in P6–P6**. The claim here is that research ethics is an obstacle to research, whether by making it more difficult to do research (P6), by slowing down research (P6*), or by making effective research prohibitive (P6**).

P6* is plausibly true. We have no good reason to believe that our research ethics systems are effective in processing applications as quickly as they could. In relation to a single research project it is true, in most cases, that research ethics slows down research, if nothing of a productive nature happens between the time of submission for research ethics approval and the time when approval is given. The project could start earlier, if researchers did not need research ethics approval or the research ethics system was faster. There is thus a crisis-

independent argument for streamlining the research ethics approval process and working to minimize the time it takes to process submissions, if we accept that most research projects generate some social value. How much a system should be streamlined would then depend on (1) it being able to maintain the quality of its processes and (2) the balance between the increased costs of running a more streamlined system and the time-saving benefits generated.

This general line of argument for more efficient research ethics processes can, however, only justify exclusive fast-tracks for COVID-19 research, if we assume either (1) that all COVID-19 projects are more important than all other research projects or (2) in "social value" terms that because we are in a public health crisis, it follows that all research projects related to relevant interventions are likely to generate more social value than all other projects and/or are more urgent. These assumptions are, however, obviously false. The expected social value and urgency of COVID-19 research will be distributed across a wide spectrum, as will the social value and urgency of other biomedical research; these spectra will have a considerable overlap and might actually completely coincide. Research into any of the diseases and conditions that cause significant loss of disability-adjusted life years globally will not suddenly become unimportant in a public health crisis.

There are two possible counterarguments available to proponents of COVID-19 fast tracks and, more generally, public health crisis fast tracks. The first counterargument is based on the premise that research ethics systems had to adapt rapidly to the COVID-19 pandemic; it was, after all, a sudden crisis and they were therefore justified in basing some of their adaptations on simple rules of thumb. It might have been better to evaluate the expected social value and urgency of each individual research project, but in a crisis situation a decision made on the binary criterion of whether a research project was related to COVID-19 or not was good enough in relation to fast-tracking.

The second counterargument is based on urgency. The basic idea is that although there is an overlap in social value between COVID-19-related and other research, COVID-19-related research was at the start of the pandemic much more urgent and should therefore be prioritized. That is, it was more important to get COVID-19-related evidence quickly than to get evidence concerning other diseases and conditions.

These counterarguments are not unreasonable, although the second relies on the somewhat problematic implicit premise that there is no other current health problem where research has the same urgency. Both counterarguments do, however, commit us to acknowledging that if fast-tracking COVID-19 projects leads to "slow-tracking" of other projects or if we completely stop processing non-COVID-19 projects for a period of time, we will create a net loss of value from the research that is approved. COVID-19 projects of little value will be processed and approved ahead or instead of other research that is of higher value.

Let us move on to considering P6 and P6**, which both claim that there are research projects that can generate large social value (following from P1–P5) that are made more difficult (P6) or prohibitive (P6**) by substantive research ethics principles or rules. Are these premises true? Yes, they are true. Some research projects would be made easier if we, for instance, were to change our

rules on compensation or payment to participants. Some would only become possible if we were to allow conscription to research, in other ways weaken requirements for voluntary participation, make it more difficult to withdraw, or abolish or weaken limits on research-related risk. However, we know from the history of research that we have good reasons for having these principles, as they inter alia prevent research likely to harm the participants and they prevent the exploitation of research subjects in the pursuit of social goods. We therefore need equally good reasons to weaken or abolish these principles. This is not an example of status quo bias; contra Chappell,[35] these principles and rules are not traditional or historical in the sense that they have no other justification than having been put in place at some time in the past. This is, instead, a requirement to provide sufficient reasons to change well-justified principles.

The following section will focus on the justification based on the large social value generated by research, and will therefore for the sake of argument assume that there are one or more promising interventions we can identify ex ante as being likely to have large social value that is likely to be actualized and where research is a necessary step in the causal chain leading to the actualization of that large social value. The problem, here, is that the protective research ethics principles we are considering changing not only protect the experiential interests of the research participants, for example, their interest in not being harmed. They also protect their right to being treated as equal citizens in society.[36] We, for instance, insist on voluntary consent because conscription to research would make some persons mere objects to be used by society in the pursuit of the social good. Similar arguments apply to some of the suggested modifications in relation to research risk and risk payments. Chappell is again forthright:

> I would further argue that, in the event that we lack sufficient volunteers to support such socially valuable but risky research, it would be ethical to financially compensate participants at whatever level of payment is necessary to make participation worthwhile for them. Such payment raises worries about exploitation via 'undue inducement'—that the prospect of payment risks inducing poorer individuals to participate against their best interests, undermining their capacity to rationally consent. While we certainly ought not to deliberately exploit anyone, it is worth stressing that *reducing* (or even eliminating) the benefits to participation seems like a very backward way to address this worry—it is unlikely to be appreciated by would-be participants, after all, and for good reason: reducing the quality of the options available to them is not a very helpful thing to do! A more helpful way to address concerns that participation might be against the interests of the participants would be to *increase* the rewards for participation, so that it is more clearly worthwhile (offering a superior risk premium than one finds for everyday risky jobs in mining and forestry, say). Given the immense social value of the research, we could—and should—sufficiently

[35] Chappell, "Pandemic Ethics and Status Quo Risk."

[36] Alex John London, *For the Common Good: Philosophical Foundations of Research Ethics* (New York: Oxford University Press, 2022).

> reward the participants for their service as to render it a 'win-win' for all involved.[37]

Here, Chappell assumes that because participation in risky research can be against the interests of participants and that we might therefore find it difficult to recruit anyone, this problem can be solved by changing the incentive structure to offer "whatever level of payment is necessary to make participation worthwhile for them." At the limit, this presumably applies to research that is known to be lethal. There will be some sum of money that will "make participation worthwhile" for at least some persons. However, any society offering that sum of money would explicitly be communicating that some citizens are worth less than others because we can pay them to die for the rest of us. We would not even be able to rely on "The old Lie: *Dulce et decorum est Pro patria mori* [It is sweet and fitting to die for one's country]."[38] Participants who die or are injured in risky research would not die or be injured due to thinking that it would be fitting to sacrifice themselves for their country; they would die or be injured because they had been induced to participate by filthy lucre.

A more charitable interpretation is that Chappell does not want to take his argument to the limit, but that he wants to have some upper limit on research risk that is higher than we currently accept. However, in the article just quoted, this does not seem to be the case. In a footnote, for instance, in relation to the involvement of older participants in human challenge studies, he states:

> Whether to include older participants depends upon how the added value of more demographically diverse research results compares (in expectation) to the higher risk they would face as individuals. If the social value of their participation is sufficiently high, then their *heroic altruism* should be straightforwardly welcomed.[39]

If Chappell intends this level of risk to be covered by the argument, it would also entail that participation would not be in a project approved by a research ethics committee or institutional review board. After consideration of the risk-benefit ratio of such a project, no committee could approve a project with known high risk but very uncertain benefits.

In other work (with Peter Singer), Chappell argues for "risk parity," that is, allowing research participants to take on the same level of risk in research as health-care professionals take on in clinical practice.[40] There are, however, important differences between the two situations relevant to the issue of payment for research. Angus Dawson points out some of these:

[37] Chappell, "Pandemic Ethics and Status Quo Risk," 68, footnotes removed.

[38] Wilfred Owen, "Dulce et Decorum Est," in Wilfred Owen, *Poems* (London: Chatto & Windus, 1920), 15.

[39] Chappell, "Pandemic Ethics and Status Quo Risk," 72n23, emphasis added.

[40] Chappell and Singer, "Pandemic Ethics."

> In Chappell and Singer's 'parity' case, they also assume healthcare workers take on any risk involved in their caring roles voluntarily. This, in my view, fails to take into account how many healthcare workers' roles involve identity issues relating to those roles and how little such roles are subject to negotiation and prior consent at the level of the individual. Being subject to risk in a professional role is just a different thing from being subject to the same amount of risk as a research participant. I don't think that the principle of risk parity can provide the grounds for the relevant justification required as the comparative cases are not truly comparable.[41]

Another important observation is that health-care workers are not in general paid a risk premium. For example, doctors and nurses working in specialties with high risks are not paid more than those working in risk-free specialties. Psychiatrists and psychiatric nurses who are at significant risk of patient violence are in general not paid more than, say, radiologists and radiographers for whom this risk is much lower. Health-care workers are not in general incentivized to take on specific risks or paid more when the risk level goes up. During the early phase of the COVID-19 pandemic, when work in intensive-care units became much more risky than normal, risk premiums were not offered for each shift taken on. Insofar as it is possible to estimate from wage data, there is no evidence for "hero pay" during the COVID-19 pandemic.[42]

People are paid to take on tasks or jobs that they would not do otherwise. Some of that payment is, in certain cases, a risk premium especially in unionized sectors,[43] but even in those cases people are not paid for taking on the risk of one particular event. Firefighters may be paid more than we pay other similarly trained emergency workers, but they are not offered extra "event risk" payment for entering a particular risky building on fire. Part of the reason for not paying for event risk is that this is likely to be exploitative and will still be exploitative, even though it makes those who take the payment and survive unharmed better off. Instead of treating people as equals, we decide to exploit already existing inequalities.[44]

From analysis of the "research ethics" premises P6–P6** in the schematic argument above, it follows, first, that changes to the research ethics system aimed at making it more effective can often be justified. However, the justification does not follow primarily from the crisis situation. The justification is primarily that there are general reasons for having an effective research ethics

[41] Dawson, "Pandemic Vaccine Trials," 9, footnote removed.

[42] Danielle Lamb, Rafael Gomez, and Milad Moghaddas, "Unions and Hazard Pay for COVID-19: Evidence from the Canadian Labour Force Survey," *British Journal of Industrial Relations* 60, no. 3 (2022): 606–34.

[43] W. Kip Viscusi and Joseph E. Aldy, "The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World," *Journal of Risk and Uncertainty* 27 (2003): 5–76.

[44] The correct analysis of exploitation is contested and beyond the scope of this essay. My own view is presented in Søren Holm, "Is Bioethics Only for the Rich and Powerful?" in *Arguments and Analysis in Bioethics*, ed. Matti Hayry et al. (Leiden: Brill, 2010), 23–36. It is worth noting that Chappell explicitly states that "we certainly ought not to deliberately exploit anyone." Chappell, "Pandemic Ethics as Status Quo Risk," 68.

system that processes all valuable research as quickly and efficiently as possible. Second, it follows that the mere promise of even very large social value is an insufficient justification for changes to substantive research ethics principles and rules, if the prior justification for these principles and rules is that they protect the basic interests of participants or their basic right to being respected and treated as an equal.

It might be argued that we could professionalize research participation and create a corps of trained research participants who are ready to participate in risky but necessary research when society faces an existential public health crisis. The analogy here could be to the most elite units of the armed forces, for example, U.S. Navy Seals or the U.K. Special Air Service. Members of these elite units of the military are trained to see it as their honorable task to take high risks, to kill or be killed in defense of their country. They are also trained to accept that their particular skills may be unneeded for long periods of time. Members of these elite units may not be paid a significant monetary risk premium, but they are paid in the coin of meaning and therefore not exploited. The problem with this suggestion is that whereas it is reasonably clear what mix of special units and military skills a country might need, given the military posture of its most likely enemies, it is much more difficult to predict what types of research and therefore research participants are needed for the next public health crisis.

The power of definition

The argument that an exceptional crisis justifies exceptional measures was widely used to justify policymaking during the COVID-19 pandemic, in research ethics and more generally. This raises interesting questions about the power to define or decide that a particular problem or issue constitutes an exceptional crisis and about the effects of entering a "state of exception."

At the international level, the World Health Organization (WHO) has the official power to declare a "public health emergency of international concern" (PHEIC) in accordance with the International Health Regulations (IHR).[45] A PHEIC can only be declared in relation to an infectious disease outbreak and is defined as "an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response."[46] A PHEIC is declared by the Director-General of the WHO on the advice of the IHR Emergency Committee and PHEIC status is reviewed every three months. Declaring a PHEIC has two main functions. First, it signals to the international community that a significant international outbreak of infectious disease is occurring. Second, when a PHEIC has been declared, the WHO Director-General can issue "temporary recommendations." These are

[45] World Health Organization, *International Health Regulations (2005)*, 2nd ed. (World Health Organization: Geneva, 2008), https://iris.who.int/bitstream/handle/10665/43883/9789241580410_eng.pdf?sequence=1.

[46] WHO, *International Health Regulations (2005)*, 9.

https://doi.org/10.1017/S0265052524000487

not legally binding, but they can include recommendations of health measures states can implement to reduce or prevent further international spread of the disease and recommendations about how to avoid unnecessary restrictions on international trade and travel. The recommendations are intended to guide state actors in order to facilitate a coordinated and proportionate international response to a given public health crisis.[47] There has for a long time been significant debate about whether the PHEIC system works and actually leads to international coordination; this debate has intensified after COVID-19.[48] Since the current version of these regulations came into force, the WHO has declared such an emergency in relation to: Swine flu (2009), Polio (2014 ongoing[49]), Ebola (2014–2016), Zika virus (2016), Kivu Ebola outbreak (2019–2020), COVID-19 (2020–2023), and Monkeypox[50] (2022–2023).

An analysis of the rationales of the IHR Emergency Committee in relation to cases from 2009–2020 where a PHEIC was declared and cases where a PHEIC was considered but not declared has shown that the IHR's three criteria are not consistently applied by the Committee.[51] The COVID-19 pandemic was, for instance, declared a PHEIC without the Committee deciding formally that it constituted "an extraordinary event" and, in the cases where a PHEIC was not declared, this particular criterion was not explicitly mentioned by the Committee. It thus seems that what does most of the work in relation to the WHO's IHR Emergency Committee PHEIC decision-making is the risk of international spread requiring a coordinated international response.

Because of the problems and weaknesses identified in the IHR and the PHEIC process, including the fact that the recommendations issued are not legally binding, the WHO member states are in the process of negotiating changes to the IHR. A new legally binding pandemic treaty is also being developed,[52] although there is no certainty that member states will be willing to cede any significant power to the WHO.[53]

Given that the WHO currently has no power to issue legally binding directions to states in relation to public health crises, a more general issue arises about the legal declaration of a state of emergency by actors that have the power to change the legal landscape. The most obvious members of this class of actors are nation-states, but the class also includes supranational bodies such as the European

[47] Jodie McVernon and Jonathan Liberman, "WHO Keeps COVID-19 a Public Health Emergency of International Concern," *British Medical Journal* 380 (2023): 347.

[48] Independent Panel for Pandemic Preparedness and Response, "COVID-19: Make It the Last Pandemic," May 2021, https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf.

[49] "Ongoing" means that the PHEIC declaration was still active at the time of writing in July 2023.

[50] Now renamed "Mpox."

[51] Lucia Mullen et al., "An Analysis of International Health Regulations Emergency Committees and Public Health Emergency of International Concern Designations," *British Medical Journal: Global Health* 5, no. 6 (2020), https://gh.bmj.com/content/bmjgh/5/6/e002502.full.pdf.

[52] World Health Organization, "Zero Draft of the WHO CA+ for the Consideration of the Intergovernmental Negotiating Body at Its Fourth Meeting," February 1, 2023, https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf.

[53] McVernon and Liberman, "WHO Keeps COVID-19 a Public Health Emergency."

Union and subnational entities such as states in federated nation-states or lower subnational entities with public health responsibilities (for example, municipalities). The legal and philosophical aspects of declarations of "a state of exception" were extensively discussed in the 1930s and 1940s in response to the rise and fall of new forms of political arrangement in Europe.[54] This topic has recently been reinvigorated in the work of Giorgio Agamben.[55] Agamben provides a historical analysis of emergency regimes from early Roman law to the present day, focusing primarily on emergencies caused by internal and external threats to political stability. He takes his point of departure in Carl Schmitt's famous observation that "[s]overeign is he who decides on the exception."[56] Agamben argues that the possibility of declaring something an exceptional emergency situation provides the political decision-maker with the opportunity to create a state of exception. The state of exception creates a new "lawless" space that can then be filled by the sovereign decision-maker.[57] The far-reaching political conclusions Agamben draws from this analysis and from his claim that we currently live in a permanent state of exception are beyond the scope of this essay, though, as is his own contentious analysis of COVID-19 public health interventions.[58]

However, Agamben's general point that emergencies open up a new space for radical decision-making by those with the definitional power to declare a state of exception is worth exploring in relation to research ethics exceptionalism. To what extent does the "fact" that something is a public health emergency warrant or justify the suspension of normal research ethics principles and their replacement by a potentially radically different research ethics? It is obvious that an Agambenian sovereign can suspend normal research ethics principles, but would it be justified?

As noted above, our current research ethics was developed as a response to problematic research practices during times of crisis. It is therefore to a significant extent protectionist and categorical. This is evident, for instance, in many of the ten statements of the Nuremberg Code. Statement 1 of the Code is an exceptionless commitment to voluntariness and consent: "The voluntary consent of the human subject is absolutely essential." Statement 5 also equally categorically states that "[n]o experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as

[54] Carl Schmitt, *Political Theology: Four Chapters on the Concept of Sovereignty*, trans. George Schwab (1922; repr., Chicago, IL: University of Chicago Press, 2005).

[55] Giorgio Agamben, *State of Exception*, trans. Kevin Attell (Chicago, IL: University of Chicago Press, 2005).

[56] Schmitt, *Political Theology*, 6.

[57] Stephen Humphreys, "Legalizing Lawlessness: On Giorgio Agamben's *State of Exception*," *European Journal of International Law* 17, no. 3 (2006): 677–87.

[58] Giorgio Agamben, "Le Due Facce del Potere," *Quodlibet*, March 17, 2023, https://www.quodlibet.it/giorgio-agamben-le-due-facce-del-potere-4-anarchia-e-politica; Carlo Salzani, "COVID-19 and State of Exception: Medicine, Politics, and the Epidemic State," *Depictions: The Paris Institute Newsletter*, March 12, 2021, https://parisinstitute.org/depictions-article-covid-19-and-state-of-exception-medicine-politics-and-the-epidemic-state/.

subjects."[59] These requirements are not stated as optional or relative to a particular context of normality. They are explicitly designed to put limits on research in a time of existential, national crisis. They are thus analogous to those articles in human rights conventions that do not have exceptions and do not allow state parties to enter derogations. In the European Convention on Human Rights the emergency provision in Article 15, for instance, allows for derogation from most articles of the Convention "[i]n time of war or other public emergency threatening the life of the nation," but explicitly prohibits derogation from Article 2 on the right to life; Article 3, which prohibits torture and inhuman or degrading treatment; Article 4.1, which prohibits slavery and servitude; and Article 7, which prohibits retrospective punishment.[60]

If we understand the most foundational research ethics principles in this way as nonderogable, it raises the question of which principles belong to this class. A full analysis of this question is outside the scope of this essay, but an initial suggestion might be that statements 1, 5, and 9 of the Nuremberg Code are core principles.[61] They protect the most basic rights of research participants against the state and researchers acting on behalf of the state, and they have been carried over into later international normative documents. Many other aspects of research ethics, including perhaps all of the specific features of the research ethics system as currently constituted, would be outside of the core and therefore in principle derogable in a true emergency. The Agambenian sovereign could thus be justified in suspending the need for research ethics committee approval, but not in suspending the right to withdraw from research or the limit on research risk.

[59] "Nuremberg Code," *Wikipedia*, https://en.wikipedia.org/wiki/Nuremberg_Code#cite_ref-ushmm_6-1.

[60] *The Convention for the Protection of Human Rights and Fundamental Freedoms* (Strasbourg: Council of Europe, 1950), https://www.echr.coe.int/documents/d/echr/convention_ENG.

[61] Statements 1 and 9 (in full) of the *Nuremberg Code* are as follows:

> 1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity… . 9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

Conclusion

This essay has analyzed to what extent a significant public health crisis, such as the COVID-19 pandemic, provides justification for changing research ethics processes, rules, and principles. It has been argued that arguments for change based on the large social value of research in crisis situations are problematic for three main reasons: (1) the ex ante estimation of the social value of research is highly uncertain; (2) some suggested substantive changes undermine the basic justification for the rules and principles; and (3) research ethics is a response to past crises, so crisis considerations are therefore already incorporated in the rules and principles. Some of the most important rules of research ethics should furthermore be conceptualized as nonderogable rights based on the principle of equal recognition of citizens. Changes to research ethics processes and systems are much easier to justify, but the justifying reasons are not crisis specific and also apply in "normal" times.

It is, however, a fact that a range of changes to research ethics systems, rules, and principles were introduced very quickly during the early phases of the COVID-19 pandemic; many more would have been introduced if policymakers had taken the philosophical and bioethical literature more seriously than they did (luckily, they did not!). This rapid modification of research ethics indicates that there is a significant need for thinking through the challenges that major public health crises raise for research and research ethics and the justifiable responses to those challenges before the next major crisis arises. How should the system respond to a change in the balance of risks between doing research and not doing research? Doing this during the last stages of or too soon after the COVID-19 pandemic may be problematic because it might lead to specific features of the COVID-19 crisis overly influencing analysis and results. Research ethicists should not be like generals "fighting the last war."[62] It is nevertheless a vital task if research ethicists want to be in a position to deliver justified "normatively heavy advice" to decision-makers during the next public health crisis.[63]

Competing interests. The author declares none.

[62] "Generals are always prepared to fight the last war" has been attributed to Winston Churchill, but it is probably apocryphal.

[63] Jonathan Birch, "Science and Policy in Extremis: The UK's Initial Response to COVID-19," *European Journal for Philosophy of Science* 11, no. 3 (2021), https://link.springer.com/article/10.1007/s13194-021-00407-z.

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