# Research Ethics and Integrity During Pandemics: Not Unique, but Vastly Magnified Challenges

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**Abstract.** This chapter sets the scene for the development of the PREPARED Code: A Global Code of Conduct for Research During Pandemics. Recalling the time when successive waves of the COVID-19 pandemic led to the deaths of millions and put health systems under enormous pressure, we explain how the pandemic created a demand for rapidly available, trusted scientific advice. Fast reaction systems, including accelerated research, faced significant ethics and integrity challenges. While most such challenges encountered during the COVID-19 pandemic were not unique, researchers and research ethics committees were ill-equipped to cope with their extent and scale. This chapter explains the purpose of the PREPARED Code against that backdrop, including what sets this code apart from many other research ethics codes.

**Keywords:** COVID-19 pandemic · research ethics · research integrity · ethics codes

## 1 The Purpose of the PREPARED Code

The COVID-19 pandemic presented the most challenging global health crisis in living memory (WHO 2022), triggering an urgent need for rapid research and innovation to address the far-reaching healthcare, social, cultural and economic consequences. Yet, amid the race to develop vaccines, treatments and public health interventions, a host of ethical dilemmas emerged (Barroga and Matanguihan 2020), exposing a significant gap in the existing frameworks governing research ethics and research integrity.

The chaotic rush to find solutions during the pandemic highlighted the critical importance of a robust ethical framework to guide research during global emergencies (Saxena et al. 2021). The need for an operational code that safeguards ethical values while supporting a swift and effective research response was crystal clear.

The purpose of this book is to explore the development of a pioneering ethics code designed specifically to support research ethics and integrity during pandemics. At the heart of the development was the premise that while research is essential during global


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health crises, it must be conducted in accordance with the highest ethical standards (Solbakk et al. 2021).

This book is an edited collection whose authors were all members of the PREPARED project team[1] that developed the PREPARED Code from September 2022 to December 2024. In the forthcoming chapters, the authors walk readers through the meticulous development of the PREPARED Code, summarising the key steps and findings.

## 2 An Ever-Changing Research Landscape

To begin, we invite you to cast your mind back to the early days of COVID-19, when successive waves of the disease led to the deaths of millions and put global health systems under enormous pressure (Independent Panel 2021). The pandemic created a demand for trusted scientific guidance that was unparalleled in its urgency (WHO 2022). People were desperate for effective treatments, preventative measures and public health interventions to counter the emerging and potentially devastating impacts of the pandemic. Researchers across all disciplines faced a unique combination of urgency, uncertainty and logistical hurdles. For those in health-related fields, most of whom had little or no prior knowledge of coronaviruses or epidemics, the race was on.

Over a period of just a few months, the research landscape altered dramatically, as the consequences of limited face-to-face contact were felt (Maison et al. 2021). Many research institutions and universities closed or significantly restricted on-site academic activities (Omary et al. 2020); almost all laboratory-based research, research with human participants and field research was stopped or suspended. New restrictions affected most research fields, including clinical trials, with most trials postponed or delayed (Shawrav 2022). As research projects faced delays, modifications or suspensions due to pandemic-related restrictions (Bratan et al. 2021), ongoing, non-COVID-19 studies experienced interruptions for unspecified periods. Across all research types, participants encountered changes to study methods (like switching to online communication). For some, such as elderly participants with cognitive impairments, continued participation was fraught with difficulties (Sharma et al. 2022).

It is clear from data available on ClinicalTrials.gov, a publicly accessible database of privately and publicly funded clinical trials conducted globally, that non-COVID-19 research, particularly in healthcare, was deprioritised in favour of pandemic-related studies. For instance, from January to May 2020, there was a marked decrease in the start of non-coronavirus trials, dropping from 2,616 trials in January to fewer than 1,500 trials in May (Xue et al. 2020). And for those that were ongoing, the number that were stopped averaged 1,147 trials per month (Gaudino et al. 2020). Meanwhile, the start of new COVID-19 related trials soared from 30 new trials in January 2020 to 784 new trials in April 2020 (Xue et al. 2020).

Research staff and resources were "purposely and purposefully" prioritised to COVID-19 activities above all else (Harper et al. 2020), as funding bodies and governments redirected resources towards COVID-19 research, impacting the availability

[1] https://prepared-project.eu/our-team/

of support for other research studies. Individual institutions also implemented new policies to address the challenges posed by the pandemic, affecting research operations and priorities (Radecki and Schonfeld 2020).

Against this backdrop, it is perhaps unsurprising that more than 50% of surveyed researchers reported poor levels of wellbeing and mental health during the COVID-19 pandemic as work changes and additional demands had a negative impact on motivation and general wellbeing (Heo et al. 2022). Furthermore, many studies reported that the burdens on some researchers, such as junior researchers and women, were greater than on others; for women, this was largely because the onus of domestic responsibilities and childcare tended to fall more heavily on them (Doyle et al. 2021).

The urgency of the crisis and the pressures upon research teams also affected the trustworthiness of research, compromising the quality, transparency and ethical standards of many research studies (Dinis-Oliveira 2020).

As researchers faced pressures to produce and publish results rapidly during the early stages of the COVID-19 pandemic, most journals in biomedicine, health and social care experienced a significant increase in the number of manuscript submissions. For example, the *Journal of the American Medical Association* reported that more than 11,000 manuscripts were submitted between 1 January and 1 June 2020, compared with approximately 4,000 during the same period in 2019, attributing virtually the entire increase to COVID-19-related manuscripts (Bauchner et al. 2020). The number of resultant publications also increased rapidly; in May 2020, *The Economist* reported that since January 2020 the number of COVID-19-related scientific publications had been doubling every 14 days, reaching 1,363 by early May (Economist 2020).

With such a high demand for publication, only a small percentage of submissions could be published in respected peer-reviewed journals, which led to a surge in preprints (studies published before peer review) (Fraser et al. 2021). While this undoubtedly facilitated rapid access to data, the fact that the preprints were not peer-reviewed allowed conclusions lacking scientific support to gain traction (Brierley 2021). Additionally, at a time when reliable evidence was desperately needed, the quality of most COVID-19 clinical studies was poor – for instance, the studies had small sample sizes or lacked rigorous methodologies – and there was a significant amount of waste in clinical research (Law and Smith 2024).

Crises can also lead to researchers cutting corners in research ethics. For instance, during the 2014 Ebola crisis in West Africa, overseas researchers carried out research among Ebola survivors without research ethics approval. This was discovered when they tried to obtain approval retrospectively in order to publish their results (Tegli 2018).

## 3 The Research Ethics and Research Integrity Response

For almost a century, research ethics has driven efforts to make science more ethical and to stop exploitation of and harm to research participants (Resnik 2018). For almost half that time, efforts in pursuit of research integrity have tried to achieve truthful science without fabrication, falsification or plagiarism (Zhaksylyk et al. 2023). Over this time, ethics guidelines have proliferated; the International Compilation of Human Research Standards, published by the US Department of Health and Human Services, lists over

1,000 laws, regulations, and guidelines governing human participants in research across 131 countries and numerous international organisations (HHS 2024). Yet the unprecedented scale and nature of the COVID-19 pandemic caught the world unprepared. While most of the specific challenges of research ethics and research integrity were not unique to the pandemic, researchers and research ethics committees were ill-equipped to cope with their extent and scale.

Research ethics committees found themselves with increased workloads; the urgency of COVID-19 research required them to expedite approvals for studies related to treatments, vaccines and public health interventions (Kebenei et al. 2024). Some committees found themselves confronting emerging ethical debates not previously encountered, for instance regarding the permissibility of human challenge studies, in which healthy volunteers would be deliberately infected with the infective agent to study the impacts of the disease in a controlled setting. Although some human challenge studies had previously been conducted for diseases like cholera, dengue, influenza and malaria, they were generally limited to well-understood infectious strains known to cause mild disease (Weijer 2024). This was not the case for COVID-19.

Debates also arose about balancing opportunities to conduct COVID-19 clinical research with the urgent need to prioritise clinical care for patients (Hashem et al. 2020). What is more, few research ethics committees already had internal policies to guide activities during public health emergencies, so most had to modify existing procedures or develop new ones and had no time to evaluate those changes (Salamanca-Buentello et al. 2024). The PREPARED consortium identified 236 new sets of ethics guidelines for the COVID-19 pandemic alone (see Chap. 4). Amid this abundance of existing codes and guidelines for research ethics and integrity, it is reasonable to ask if we need another – and, if so, why.

## 4 What is Different About the PREPARED Code?

This book is about yet more ethics guidance, the PREPARED Code: A Global Code of Conduct for Research During Pandemics. But it is ethics guidance that stands out in five ways. The PREPARED Code:

1. focuses on one very specific area, *research during pandemics*, which makes it easy for researchers from any discipline to find guidance quickly and easily should the need arise
2. is short and jargon-free (unlike most ethics guidance), thereby enhancing accessibility
3. is based on significant, global research undertaken in nine languages to identify real-world challenges during pandemics
4. is values-driven to motivate users to understand why they should comply with the guidance articles, for instance the need to take care that additional responsibilities during pandemics are distributed fairly and in a way that does not exacerbate existing inequities
5. combines research ethics and research integrity advice to stop the silo-building that divides these two sister disciplines and results in their generally being addressed as if they were separate entities rather than two sides of the same coin, both concerned with doing the right thing in research.

The approach used for the development of the PREPARED Code was previously applied in the development of The TRUST Code: A Global Code of Conduct for Equitable Research Partnerships (TRUST 2018). One could venture to call the TRUST Code, launched in 2018, the most successful ethics code of the past ten years, given its rapid endorsement by high-profile adopters from around the world, including research funders, the European Commission, the European & Developing Countries Clinical Trials Partnership, the Dutch and Polish governments, and the publishers *Nature* and Sage across their entire portfolios (European Commission 2018; Nature Medicine 2023).

This book introduces the PREPARED Code as follows:

**Chapter 2** presents the PREPARED Code in its final form, the end product of a long and in-depth development process.

**Chapter 3** focuses on explaining and justifying the guiding rationale of the development process. It explores the conceptual foundation of the PREPARED Code, including why a risk-based and values-driven approach was taken, and why research ethics and research integrity are combined in one code.

**Chapter 4** describes the broad research foundation on which the PREPARED Code was built, including literature reviews of the challenges related to COVID-19 in nine languages, scoping reviews on other epidemics and pandemics, special group reports for vulnerable persons, a human rights report, and the identification and analysis of related ethics guidance documents.

**Chapter 5** outlines the methods that were employed at each stage of development to elucidate how the code was built, from the identification of the risks to research ethics and integrity during pandemics to the iterative and broad consultation applied in refining the resulting code.

**Chapter 6** describes the implementation support developed to help people understand the pandemic-related ethics and integrity challenges and how to apply the PREPARED Code, including tools like a specially designed app that guides the learner through a wide range of relevant case studies.

**Chapter 7** synthesizes the learning from a broad range of activities to develop a code of conduct to guide research during pandemics. The chapter includes our recommendations for future developers of ethics codes to help ensure effectiveness and credibility.

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