



# Ensuring Effectiveness and Credibility: The Conceptual Foundation of the PREPARED Code

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**Abstract.** This chapter explains the conceptual foundations of the PREPARED Code, which together provide the credibility required to justify adding yet another ethics code to the thousands that already exist. The code is built on real-world risks identified in nine languages rather than, for instance, on drafters' expertise, thereby making it as precisely honed an instrument as possible to cope with the real-world ethics and integrity challenges experienced during a pandemic. The code is values-driven, focused on the values of fairness, respect, care and honesty, to harness the motivational power of moral values and to provide an easily understandable, globally applicable moral framework. Unlike most other ethics codes, the PREPARED Code unites research ethics and research integrity guidance into one, to ensure that a culture of integrity rather than a box-ticking mentality is fostered. The short, jargon-free code text addresses all research disciplines and, most importantly, it is based on extensive input from a wide range of stakeholders, including highly marginalised populations, to ensure that it is fit for purpose.

**Keywords:** Research ethics · research integrity · pandemic ethics · ethics codes

## 1 Introduction

Drafting an ethics code is something anyone can attempt, but crafting a code that is effective and credible demands thoughtful attention to a variety of factors. An effective ethics code serves not just as a set of rules for guiding conduct, but also as a practical and inspirational tool for fostering a culture of integrity. Additionally, those who use an ethics code need to trust that it is fit for purpose and can serve the interests of all stakeholders. How can this be ensured?

While the visible *product* of development, the resultant ethics code, becomes the familiar tool, it is the behind-the-scenes *process* of code development that confers credibility (Messikomer and Cirka 2010). Thus, the short and concise PREPARED Code

presented in Chap. 2 may look as though it was quick and easy to develop, but it is underpinned by a significant body of work that was guided by a clear and coherent rationale.

This chapter focuses on explaining and justifying the guiding rationale for the development process. In other words, it explores the conceptual foundations of the PREPARED Code, addressing “why” rather than “how” questions, including:

- *Why is the PREPARED Code built on real-world risks?* Section 2 examines different approaches to developing ethics codes, including top-down and bottom-up methods, and explains why a bottom-up, risk-based approach was selected.
- *Why is the PREPARED Code values-driven?* Section 3 explains the advantages of values-driven moral frameworks over mere rules-based systems. It also addresses why the moral values of fairness, respect, care and honesty serve as the pillars of the code.
- *Why are research ethics and research integrity integrated in a unified code?* Section 4 outlines the differences, commonalities and complex interplay between research integrity and research ethics. It also clarifies the advantages of combining research ethics and research integrity in one code, especially during a pandemic, rather than regarding them as separate silos.
- *Why does the code take a broad and inclusive approach to development?* Section 5 examines why the wider social, economic and cultural contexts in which pandemics occur were considered, stressing the importance of addressing intersecting vulnerabilities. Additionally, the imperative of inclusivity in the code’s development was emphasised, ensuring that the voices of *all* stakeholders, especially marginalised populations, were heard and their views reflected in the code.
- *Why is the PREPARED Code short, jargon-free, multidisciplinary and focused?* The chapter ends with an explanation of the relationship of the PREPARED Code to its sister code, the TRUST Code (TRUST 2018), to show why a short, jargon-free and focused code that addresses all academic disciplines can succeed among a proliferation of ethics guidance.

## 2 Approaches to the Development of Ethics Codes

Various approaches have been utilised to create ethics codes, each employing distinct methodologies that come with their own strengths and limitations. In this section we consider the main methods that can be used and explain the decision to use a risk-based approach plus extensive consultations for the development of the PREPARED Code. The four approaches are summarised in Fig. 1.

Approaches to drafting ethics codes can be broadly distinguished as “top-down” or “bottom-up”. Of the top-down approaches, the most common and well-known method is the *drafter-based approach*, which relies upon the drafters of an ethics code or legal document to identify the main content (for example, the challenges to be addressed) as well as the underlying principles or values.

This approach is likely to have been used for the UN (1948) Universal Declaration of Human Rights. For instance, when South African Prime Minister Jan Christiaan Smuts suggested lines for the preamble in 1945, he referred to “fundamental human rights”



**Fig. 1.** Possible approaches to ethics code development

and “the sanctity and ultimate value of human personality”. Yet the drafters changed “sanctity” to “dignity” to achieve the broad consensus required (Tiedemann 2006).

Another top-down approach to developing an ethics code can be termed the *code-based approach*, as it involves analysis of existing ethics codes and documents to decide what is relevant to the development of new guidance. This approach is often used alongside a drafter-based method, with a code-based version being produced as a starting point that the drafters subsequently revise.

For both drafter-based and code-based methods, the development of ethics guidance documents is centralised and reliant upon representatives of international bodies, professional organisations and experts having the relevant knowledge and experience. Consequently, while top-down ethics codes are representative of the opinions of experts, especially those from the research governance community, they might not incorporate the opinions and experiences of other important stakeholders. Hence, the major shortcoming of these two top-down approaches is that they rely upon the viewpoints of a group of drafters. In the case of code-based approaches, this is because (at least some of) the codes and guidance used to inform the new code will themselves have been developed using the drafter-based approach.

By contrast, ethics codes can also be developed via bottom-up approaches that proactively seek to represent the experiences and opinions of a wide range of stakeholders. For instance, citizen-driven approaches are increasingly used across a variety of domains, such as innovation and policymaking (Paleco et al. 2021; Huttunen et al. 2022). However, a purely citizen-driven approach to development was not considered suitable for the PREPARED Code because very few citizens will have experience of research ethics and research integrity challenges during pandemics. To be effective, ethics codes must address real-world challenges rather than those of a hypothetical or speculative nature.

Thus, an alternative bottom-up approach was taken, involving considerable effort to reveal real-world research ethics and research integrity challenges and corresponding risks arising in the context of pandemic research. Rather than consulting experts, existing codes or citizens to identify the matters to be included in the code, the PREPARED team identified real-world research ethics and research integrity issues that had actually occurred from published materials in nine languages (English, Chinese, French, German, Hindi, Japanese, Korean, Russian and Spanish), as well as from studies with certain groups who were likely to have been disadvantaged during the COVID-19 pandemic (in

particular disabled people, health and social care workers, people on the poverty line and women). (For details, see Chap. 4.) This risk-based approach to the identification of matters that raise ethical issues for research during pandemics meant that the resultant code was evidence-informed, and this helped to ensure its pragmatic value because it was grounded in real-world experience.

The risk-based approach has become prominent across a number of policy domains, including public health, finance and disaster management, as a method to allocate resources efficiently and to address high-priority risks (Rothstein et al. 2013). This is because risk-based approaches can help to align governance goals with levels of risk, supporting rational decision-making and institutional accountability (Graham 2010). Unlike drafter-based approaches, which often rely on subjective expertise, the risk-based method employs systematic evaluations, enabling more objective, data-informed decisions (Black and Baldwin 2010). The approach also integrates the precautionary principle, which advocates preventive action in the face of scientific uncertainty (Khodadadyan et al. 2021).

It is important to note, however, that the four approaches are not mutually exclusive. For instance, the recent revision of the World Medical Association (WMA) Declaration of Helsinki (WMA 2024b), which outlines the ethical principles for medical research involving human participants, combined a drafter-based approach with very significant external consultations, thereby using elements of the citizen-driven approach. The workgroup entrusted with the ninth revision of the declaration included representatives from 19 countries and invited advisers with expertise in bioethics. Over the course of 30 months, the workgroup received feedback from partners, including WMA members, who provided comments on the draft text during two public comment periods. Additionally, eight regional meetings were held across all WMA regions. Ultimately, the refined draft of the declaration was unanimously adopted by the 50 delegates at the General Assembly of the WMA in October 2024, marking 60 years since the original declaration was adopted (Resneck 2024; WMA 2024a).

For the PREPARED Code, risk-based analysis *drove* the development. However, the code authors also included elements from the code-based and citizen-based approaches. (See Chap. 5 for the extensive, including public, consultations and Chap. 4 for the gap analysis using existing ethics codes relevant to pandemics.) Nevertheless, we believe that the risk-based approach should precede all other approaches to produce an effective, evidence-informed code. That is because risk-based approaches are closest to real-world challenges.

In the next section we explain why the PREPARED Code is values-driven, and why the moral values of fairness, respect, care and honesty serve as the pillars of this code.

### 3 A Values-Driven Code

Just as there are various approaches that could have been taken to code development, there are also various ethics frameworks that might have been adopted. For instance, ethics codes and guidance documents can be rules-based, principles-based or human-rights-based, with guidance statements designed in alignment with certain moral rules, moral principles or human rights. Box 3.1 indicates the distinctions that were drawn

between rules, principles, values and virtues for the development of the TRUST Code (TRUST 2018) and the PREPARED Code. Other interpretations are possible.

**Box 3.1 Rules, Principles, Values and Virtues**

- *Rules* are universal directives that specify what is permissible and what is forbidden. Actions are deemed “morally correct” if they align with specific moral rules, such as “do not kill”, regardless of the outcome.
- *Principles* are behavioural rules for action in specific situations. When the principle is known, it is clear what to do. For instance, *in dubio pro reo* is a principle which requires that people be treated as innocent until proven guilty.
- *Values* can be mathematical; they can refer to things people desire (i.e. value), e.g. money or glory; or they can be moral values, i.e. guidance for doing the right thing, such as trying to be fair.
- *Virtues* and values often refer to the same moral entity, e.g. fairness, but in the case of virtues, they are ingrained solidly in a person’s character, which does not have to be the case for values.

The decision to adopt a values-based framework for the PREPARED Code was taken for the reasons outlined below.

We believe that there is a limit to the usefulness of principles- or rules-based research ethics and research integrity approaches and frameworks. Ethicists have long contended that systems based solely on rules or principles, without incorporating agent-centred virtues or values, can be deeply problematic because they disconnect moral behaviour from the individual’s character and intrinsic motivations (Johnsson et al. 2014). Rules alone do not motivate to action (Dawson 1994), especially if the potential outcomes do not appear to be right or fair.

When set solely within a compliance-based framework, research ethics and research integrity can seem like a box-ticking exercise, reducing ethical responsibility to a mere checklist (Pennock and O’Rourke 2017). Thus, of recent years, particularly in the domain of research integrity, there has been a notable shift towards the promotion of virtue ethics (Banks 2018), with the assumption that this agent-centred approach will serve to engender moral character and a greater sense of personal responsibility in researchers (Mitchell 2015). An agent-based ethics framework offers an alternative to exclusively rules- or principles-based methods. In line with this shift, the underpinning ethics framework for the PREPARED Code promotes an agent-centred approach, albeit via moral values rather than virtues.

We accept that the nature of the relationship between moral values and virtues is a matter of debate, but our stance assumes that a values approach and a virtues one might be regarded as different points along the same trajectory (Chatfield and Law 2024). For instance, if a person cultivates the value of honesty, it might eventually become a virtue of that person, virtues being embedded moral values. In the main, the development of moral virtues relies upon habit. Eventually, through much practice, habits become character traits of the virtuous individual (Aristotle 2009). While the development of the virtuous researcher is an admirable goal, it might – given that it takes years of dedication and practice – feel exclusionist to a young researcher. Alternatively, a values approach can tap into (hopefully) existing moral values that resonate with even a novice researcher.

Significantly for research ethics and research integrity, a defining characteristic of personal values is their motivational power. This applies especially to values with explicit moral significance, which are often regarded as the most important in moral motivation (Schwartz 2012). People hold their moral values in high esteem, allowing them to shape

behaviour and decision-making profoundly (Schroeder et al. 2018). They guide decision-making, inclining us towards one course of action over another (Ogletree 2004). Moral values are especially important for directing ethical choices. For example, holding fairness as a core value *motivates* us to treat people fairly and incorporate fairness into our decision-making.

The most prominent example of a values-based approach in research ethics is found in the TRUST Code (TRUST 2018), which is grounded in the values of fairness, respect, care and honesty. While other moral frameworks are regularly criticised as overly Western or Anglo-Saxon, especially systems that accord “autonomy” intrinsic value (Varelius 2006), the TRUST Code has been adopted around the world. It is used globally to guide equitable research partnerships (Chatfield and Law 2024) and its widespread adoption may be attributed to three main factors:

1. The four values of fairness, respect, care and honesty are straightforward and accessible, requiring no technical expertise to be understood.
2. They were identified as components of a moral framework through a bottom-up process, avoiding bias toward high-income country perspectives (Schroeder et al. 2018).
3. The framework was developed by a diverse global team, including representatives from vulnerable populations (*ibid*).

Nevertheless, while the TRUST values had resonated globally, their applicability to the PREPARED Code could not be assumed. Prior to the identification of the wide-scale research ethics and research integrity risks encountered during pandemics, alignment of the risks with the TRUST values was purely a matter of speculation. Nevertheless, as described in Chap. 5, it soon became clear, during the process of risk analysis for the PREPARED Code, that *all* of the identified pandemic-related risks for research ethics and research integrity could be aligned with at least one of the four TRUST values. In other words, the identified breaches of research ethics and research integrity that emerged or were exacerbated during pandemics could all be associated with lapses or failures in fairness, respect, care and/or honesty.

Explanation of the four values within the context of research is articulated elsewhere (Schroeder and Chatfield 2018; Schroeder et al. 2018; Chatfield and Law 2024), but it is easy to imagine why fairness, respect, care and honesty are also important in the context of a pandemic as illustrated in Fig. 2.

While the values of fairness, respect, care and honesty can provide a moral framework to guide ethical research during a pandemic, it is not always easy to understand how values should be applied in specific situations. Thus, both the TRUST Code (TRUST 2018) and the PREPARED Code include guidance articles that help to operationalise the values. The PREPARED Code lists 27 articles: six for fairness, seven for respect, eight for care and six for honesty. (The process of alignment of articles and values is described in Chap. 5).

This linkage makes it easier for PREPARED Code users to understand the relationship between their values and the action-guiding articles. For instance, by attempting to continue community engagement during a pandemic, researchers can be sure that they are enacting fairness.



**Fig. 2.** A world of fairness, respect, care and honesty during pandemics

Now that the reasons for adopting a risk-based and values-driven approach to code development have been explained, the next section explains why the PREPARED team integrated research ethics and research integrity in a unified code.

#### 4 Research Ethics and Research Integrity in the Same Code?

The PREPARED Code is different from most other codes or guidelines for responsible research in that it addresses matters of both research ethics and research integrity in one code. This is highly unusual, as they are more ordinarily viewed as distinct concepts that require discrete regulation (Kolstoe and Pugh 2023). To understand why this is so, it is helpful to consider the provenance of research ethics and research integrity.

It is often repeated that research ethics was “born in scandal and reared in protectionism” (Levine 1988; see also Reverby 2012; Dhali 2014), thanks to shocking revelations about unethical research that shaped attitudes, guidance and legislation around research ethics significantly. For instance, the Nuremberg Code was developed in response to the horrific medical experiments conducted by Nazi doctors during World War II (Annas and Grodin 2008). It became the first internationally recognised guidance document in research ethics, emphasising the requirement for informed consent and the duty to protect participants from harm.

Nowadays the term “research ethics”, in the broadest sense, is applied to all issues of a moral nature that are associated with the planning, conduct, dissemination and impacts of research. Additionally, beyond the participation of humans, research ethics also governs aspects such as harm to animals or the environment, dual use (the use of research results by both civilians and the military), misuse, impacts upon societies (e.g. from AI technologies) and impacts upon communities (e.g. ethics dumping, which is the offshoring of unethical research from higher-income to lower-income regions (Schroeder et al. 2018)).

Similarly, over the past thirty years a growing level of concern around the integrity of research has been driven by scandals including unsafe practices, the falsification of data and concerns about the reliability of research outputs. For instance, in the late 2000s, news emerged about scientific misconduct involving researcher Anil Potti, who fabricated and falsified data in cancer studies in the United States. Potti’s false claim to have developed a method for personalising cancer treatments (Ince 2011) revealed a lack

of independent validation of data and insufficient oversight of clinical trials (Kurzrock et al. 2014).

Around the same time, revelations about Hwang Woo Suk’s fabrication of results in cloning and stem cell research prompted international guidelines emphasising transparency, reproducibility and peer review (Franzen 2016; Wilson 2020).

Thus, instances of research misconduct like these research ethics scandals led to the development of governance procedures.

Research misconduct does not just lead to lost time, lost resources and damaged reputations (Committee on Science, Engineering, and Public Policy 2009:18).

The consequences of research misconduct can be severe including preventable illness or the loss of human life due to misinformation in the literature or continued citing of retracted work. (Imperial College London n.d.)

Today, the term “research integrity” is associated with “the conduct of research” in ways that “promote trust and confidence” in “all aspects of research” (UKRIO 2023). When researchers conduct their research with integrity, this enables the global research community and society to have confidence and trust in the methods *and* the findings of the research (Dove 2024).

While being “born in scandal” (Levine 1988) applies to both fields, research ethics and research integrity have become generally regarded as discrete entities with separate journals, separate conferences, separate professional networks and often separate training units (Chatfield and Law 2024). Table 1 lists some examples of commonly perceived differences between research ethics and research integrity.

**Table 1.** Summary overview of perceived differences between research ethics and research integrity

	Research Ethics	Research Integrity
Main purpose	Protection of rights and welfare of participants	Trustworthiness of science
How governed?	Research ethics committee approvals and monitoring	Research integrity institutional frameworks, boards and officers
Training	Process focus, with rules and principles	Agent focus, with virtues and values
Timing	Prospective assessment (before a study)	Retrospective assessment (after a study)
Research quality	The focus not on scientific quality	The primary focus on scientific quality

The examples above serve to illustrate why the two fields are often governed separately, but the differences listed in Table 3.1 are oversimplified. In practice, the lines of division between research ethics and research integrity are often blurred. Taking research quality as an example, an ongoing question of research ethics committees has

been whether bad science equals bad ethics (Dawson and Yentis 2007). As became starkly apparent during the COVID-19 pandemic, conducting trials whose ultimate failure to answer the research question is foreseeable (e.g. because the trials are not large enough to provide a definitive result) is not only a waste of resources but also a breach of research participants' trust and a violation of research ethics (Law and Smith 2024).

Even though there may appear to be clear differences between research ethics and research integrity, there is also a significant overlap. Overlapping issues include conflicts of interest, the social value of research, data protection, open science and data sharing (ENERI Classroom n.d.), which is particularly relevant in the context of a pandemic.

Further, a direct relationship between the two is implied by the tendency to use "research ethics" as an umbrella term. For instance, in Norway "integrity" is included as one of the main features of the general principles of research ethics (Kaiser et al. 2022).

Most significant, however, is that research ethics and research integrity are inextricably linked via the values, intentions and actions of the person undertaking any research (the researcher). Researchers must accept that they act as moral (or immoral) agents. When researchers adopt the appropriate moral values/virtues, they strive to comply with requirements of both research ethics *and* research integrity (Chatfield and Law 2024).

While the credibility of a values-based code for research ethics has been demonstrated through the wide-scale adoption of the TRUST Code (TRUST 2018), this approach is new for a research integrity code. To understand why we believe the approach might also be effective for research integrity, it is helpful to consider why there were challenges to maintaining the integrity of research under the pressure of the COVID-19 pandemic.

Globally, the COVID-19 pandemic led to a surge in research output, with scientists rushing to publish findings about the virus, its transmission and potential treatments. The increase in volume, together with the accelerated pace, resulted in a flood of research publications, not all of which were of high quality. Concerns were soon raised about the reliability of findings and the potential for compromised peer review processes (Dinis-Oliveira 2020; Morens and Hammatt 2021; Lipworth et al. 2023; Evans et al. 2024). Fast-tracked research was associated with a decrease in rigor and quality, a rise in non-peer-reviewed publications and a competitive culture (Smith et al. 2023).

The increased use of open platforms for data sharing facilitated the rapid sharing of information, but also magnified risks. Data and research findings often bypassed traditional quality control measures, which enabled the spread of poor-quality studies across social media and other platforms. The rapid dissemination of flawed research not only harmed scientific credibility, but also contributed to misinformation (Dinis-Oliveira 2020; Evans et al. 2024).

The pandemic further exposed and exacerbated existing inequalities in the research ecosystem. For instance, questions arose about the continuation of non-COVID-19 studies and resource allocation (Lipworth et al. 2023; TENK 2024). Researchers working on non-COVID-19 projects faced limitations due to lockdowns and social distancing measures, which affected study completion and publication opportunities (Smith et al. 2023).

This imbalance perpetuated systemic inequities, both within research teams and globally. Teams and institutions in higher-income countries benefited disproportionately from well-established infrastructures, which enabled them to accelerate studies and

share data more effectively than their counterparts in lower-income countries. Such disparities reinforced an already unequal playing field, raising concerns about equity and representation (Evans et al. 2024). While the pandemic initially fostered collaboration, travel restrictions and geopolitical tensions later hampered international research efforts (Smith et al. 2023).

During the COVID-19 pandemic, many researchers and research teams were placed under additional pressures for which they were not prepared and in facing which they were generally unsupported. Even within research teams, hierarchical disparities were accentuated as some already disadvantaged researchers bore heavier burdens than others (Inguaggiato et al. 2024). And pressures take their toll.

Numerous studies have indicated that the propensity to engage in research misconduct is associated with external pressures (Grimes et al. 2018; Houle et al. 2023). It is not that researchers do not understand that it is wrong to falsify data or exaggerate findings; it is rather that they tend to rationalise exceptions for themselves (Sticker 2017). Hence, the recommendation that an agent-based approach is needed to engender a greater sense of personal responsibility (Mitchell 2015). A values-based research integrity code is aligned with this thinking.

The PREPARED Code therefore has an ambitious aim in combining research ethics and research integrity in one code. It motivates researchers to act ethically by aligning the values between research ethics and research integrity to ensure moral clarity (Chatfield and Law 2024). By embracing the values of fairness, respect, care and honesty, researchers facilitate a culture in which both research ethics and research integrity can flourish.

## 5 Taking a Broad and Inclusive Approach to Code Development

In 2022, *Nature* adopted the TRUST Code to address helicopter research and ethics dumping across its entire science publishing portfolio (Nature 2022). In a podcast, Dr Sowmya Swaminathan, Nature's Director for Diversity, Equity and Inclusion, explained that the TRUST Code is

a framework that's based on four values of fairness, respect, care, and honesty. It's a very comprehensive framework .... But at the same time, it's also designed in a way so as to make it relevant across multiple disciplines. So these are actually the elements that drew us to the code – the fact that they took such a broad, consultative approach, that they integrated the perspective of vulnerable populations, and that it is designed to be relevant across multiple disciplines (Kenneally 2022).

A very broad consultative approach and the integration of the perspectives of people in vulnerable situations were taken very seriously in the drafting of the TRUST Code, and also the PREPARED Code (see Chap. 5). This was important for the following reason. The PREPARED Code is built on 160 real-world risks in research ethics and research integrity as identified via the literature in nine languages. However, an obvious criticism of this approach is that the concerns of the least advantaged about matters involving research ethics and research integrity might not reach the academic literature. That is why broad consultations, including with the “Nairobi sex workers” and representatives

from the South Africa San Council,<sup>1</sup> were key to building an inclusive ethics code. (For more information on the consultations, see Chap. 5.)

“Nairobi sex workers” is the term used by the PREPARED team for the more than 40,000 sex workers who are registered in ten foreign-funded research clinics in and around Nairobi that seek to prevent and treat HIV and other sexually transmitted diseases. Most of the sex workers have no income or support other than the meagre income derived from sex work. They live in small tin shacks, work well into middle age and accept dozens of clients every day because the payment from each is very low (Lucas et al. 2013). The COVID-19 pandemic seriously worsened the situation of this already highly marginalised group. In particular, increased poverty due to the loss of livelihoods brought about by COVID-19 restrictions led to heightened risk-taking behaviours, which in turn exacerbated their stigma (Schroeder et al. 2024).

The research foundation that represents the interests of the Nairobi sex workers in the PREPARED team (Partners for Health and Development in Africa, Kenya) has its own significant budget and was part of the team from the proposal-writing stage to the current dissemination phase.

The PREPARED team went one step further than the drafters of the TRUST Code, because pandemics impose extreme *additional* social and economic burdens, which the team also wanted to capture. Consequently, in addition to risk-identification from published literature and broad consultations, general challenges for the following (presumably disadvantaged) groups were scoped:

- sex workers in Nairobi informal settlements, the “Nairobi sex workers”
- health and social care workers in the United Kingdom and South Africa
- disabled people in the United Kingdom
- women researchers
- highly impoverished people in India.

The findings from these activities, summarised in Chap. 4, do not focus on research ethics and research integrity alone. A multitude of social and economic challenges were identified, including starvation during lockdowns (Kapoor 2020), the worsening of existing exclusions for disabled people (Partington et al. 2023) and the disproportionate burden on women, including women researchers (Inguaggiato et al. 2024), during the COVID-19 pandemic.

One might argue that such a broad view is unnecessary when writing a code primarily intended for use by researchers, research ethics committees and research integrity offices. However, the problems of the disadvantaged during the COVID-19 pandemic should not be ignored. Two critical lessons emerged from the PREPARED team’s activities:

First, approaches to dealing with a pandemic in a high-income country must not be replicated uncritically in a lower-income setting. For instance, the COVID-19 lockdown the Kenyan government initiated, following the lead of governments in higher-income

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<sup>1</sup> The government-recognised South African San Council was formed in 2001 to represent the interests of three major San communities, indigenous groups or First Peoples in South Africa. They were invited advisers at two PREPARED conferences and contributed to the PREPARED Code.

countries, had far-reaching consequences for the Nairobi sex workers, who were ill-equipped to deal with them.<sup>2</sup>

Second, the distribution of life-saving vaccines must be undertaken more equitably during future pandemics. A poignant example of inequity during the COVID-19 pandemic saw healthy adults in high-income countries being given booster doses of the vaccines while even medical staff in lower-income settings remained unprotected (COVAX 2022).

What impact did this very broad approach have on the PREPARED Code? Unlike the TRUST Code (TRUST 2028), the PREPARED Code is prefaced with a vision statement: “Pandemic research should be trustworthy and the results accessible to all.” But there were also direct impacts on specific articles. Without the broad approach to ethics code development described above, Articles 6 and 8 might not have been included. Article 6 arises from the exacerbation of existing inequalities that occurred during the COVID-19 pandemic, especially for women researchers (Inguaggiato et al. 2024), something that should be avoided in future pandemics. Article 8 draws attention to the fate of community researchers, who can make a modest living by assisting researchers. During the COVID-19 pandemic, they were often classed as civilians, rather than researchers, and consequently lost access rights to research sites and related income during lockdowns. Article 8 of the PREPARED Code tries to preclude this from happening during the next pandemic. The direct impact upon the code shows that the broad approach was worth taking.

## 6 Short, Jargon-Free, Focused and Multidisciplinary

Codes for research ethics and research integrity come in all shapes and sizes. We are not suggesting that they should all look like the PREPARED Code. However, there are several reasons why the PREPARED team opted for a focused, short, jargon-free and multidisciplinary code.

First, it is important to remember that during pandemics, researchers who act unethically or without integrity may cause serious harm to research participants and others (Resnik 2024). Research ethics guidance specific to the challenges of the COVID-19 pandemic was hard to find, and it was needed in a hurry (Meagher et al. 2020). A short, focused and multidisciplinary code ensures that researchers from all fields can find – quickly and easily – guidance on aspects of responsible research specific to pandemics.

Secondly, keeping the code jargon-free helps reduce confusion and ensure that it is understandable across disciplines, and across a range of stakeholders. Ease of understanding is important, not just for researchers, research ethics committees and research integrity offices, the main target audiences of the PREPARED Code, but also for other users, such as research funders and sponsors, as well as research participants, NGOs and

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<sup>2</sup> A short video produced by the PREPARED team in Nairobi can be seen at <https://youtu.be/WwghcJr1F74>. With 45,000 views at the time of writing (January 2025), this video is by far the most successful of the PREPARED project videos, indicating that it is beneficial when ethics projects do not stand back from ethics issues outside of their immediate focus.

the media. Brevity, simplicity, clarity and user-friendliness are highly valued in research ethics procedures:

Whatever is brief and clear is better than what is not and saves time. What is simple and user-friendly is better than what is not even though the two have the same aims because it saves both time and mental energy. (Ouwe Missi Oukem-Boyer et al. 2016:1).

Additionally, a short and jargon-free ethics code can help research participants and NGOs resist unethical research, thereby providing a bottom-up tool to facilitate ethical research. For instance, the TRUST Code sparked the development of a sister code driven by an NGO, the South African San Council, which is now used in South Africa to stop exploitative research involving the Indigenous San (Schroeder et al. 2018 p. 21). Also, the PREPARED Code has already been translated into Swahili for use in the Nairobi clinics that are associated with the PREPARED project. The fact that the code is short and accessible enables its use with potential research participants.

Lastly, the PREPARED Code is multidisciplinary, though it is not intended to replace all other codes and guidelines for research ethics and research integrity. Most disciplines have their own tailored codes of research ethics: for instance, for physiologists who use animal experimentation, or for psychologists who conduct research with people who have mental health problems. These codes continue to apply during pandemics. Rather, the PREPARED Code is intended to *complement* other relevant codes of ethics and integrity. It provides guidance on issues that are exacerbated during pandemics.

To this end, the PREPARED Code does not replicate what already appears in the TRUST Code or the European Code of Conduct for Research Integrity, even though the risks of inequitable research and breaches of research integrity are likely to increase during a pandemic. Instead, these two codes are mentioned in the preamble to the PREPARED Code. Likewise for the Declaration of Helsinki, the primary source of ethics guidance globally for medical research involving humans (WMA 2024b), which itself might be regarded as brief and focused guidance.

For these reasons, and given the widespread and swift adoption of the TRUST Code, which is recognised for its brevity and user-friendliness, we hope that the PREPARED Code provides significant added value amid an abundance of existing ethics guidance.

## 7 Conclusion

For an ethics code to be effective, users must have confidence in its purpose and trust that it serves the interests of all stakeholders. But why should a new code enjoy trust? Given that there is no body of evidence to prove its worth, the answer to this question lies in the behind-the-scenes work of code development. The process of code development confers credibility (Messikomer and Cirka 2010), and knowing how a code was developed is a prerequisite to measuring its effectiveness (Kaptein and Schwartz 2008). Consequently, in this chapter we have sought to explain the guiding rationale for the development of the PREPARED Code and the inbuilt measures to help maximise its effectiveness and credibility.

The PREPARED Code is different from most other codes in a number of respects: it is risk-based, values-driven, multidisciplinary, short and jargon-free, it was developed in a highly inclusive process, and it is applicable to both research ethics and research integrity (Fig. 3). These factors enhance both the effectiveness and the credibility of the code.



**Fig. 3.** Measures to maximise the effectiveness and credibility of the PREPARED Code

The risk-based approach ensures the practicality and relevance of the PREPARED Code because it addresses real-world challenges that have occurred during pandemics. The alignment of the code with core moral values that resonate among people globally means that the code is more than simply a box-ticking exercise; it also serves to motivate and inspire users. The fact that the code is multidisciplinary, short and jargon-free means that when needed, research ethics and research integrity guidance is easy to find, and readily accessible to researchers and non-researchers alike. Finally, broad inclusivity is essential, not only for credibility (Messikomer and Cirka 2010), but also to ensure that the voices of the most disadvantaged are represented meaningfully.

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