# Bioethics and scientific integrity in clinical research on Covid-19

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**Abstract**

The emergence of Covid-19 has led the scientific community to undertake much research to contain the disease. In six months of pandemic, numerous articles were published, even without peer review, which puts their integrity under scrutiny. In view of this problem and based on the literature and legislation, this article analyzes the ethical and bioethical impacts of the urgency of research and to identify the vulnerability of individuals in a pandemic. We conclude that ethical integrity and the observance of bioethical principles in clinical research are essential, regardless of the need to speed up research in this case, considering the scientific method and the vulnerability of those involved, based on the bioethics of protection.

**Keywords:** Bioethics. Scientific integrity review. Coronavirus infections. Health vulnerability.

**Resumo**

**Bioética e integridade científica nas pesquisas clínicas sobre covid-19**

O surgimento da covid-19 levou a comunidade científica a empreender muitas pesquisas para conter a doença. Em seis meses de pandemia, inúmeros artigos foram publicados, mesmo sem avaliação por pares, o que coloca em xeque sua integridade. Diante desse problema, com base na literatura e na legislação pertinente, este artigo se propõe a analisar o impacto ético e bioético da urgência da pesquisa e identificar a vulnerabilidade dos indivíduos em tempos de pandemia. Conclui-se que a integridade ética e a observância dos princípios bioéticos nas pesquisas clínicas são centrais, evidenciando que, apesar da necessidade de agilizar os processos de investigação, todas as etapas devem ser cumpridas, e a vulnerabilidade dos participantes deve ser considerada pela ótica da bioética de proteção.

**Palavras-chave:** Bioética. Revisão de integridade científica. Infecções por coronavirus. Vulnerabilidade em saúde.

**Resumen**

**Bioética e integridad científica en la investigación clínica sobre covid-19**

La aparición de la covid-19 ha llevado la comunidad científica a emprender muchas investigaciones para contener la enfermedad. En seis meses de pandemia, se han publicado numerosos artículos, incluso sin revisión por pares, lo que pone en jaque su integridad. Ante esta problemática, a partir de la literatura y la legislación pertinente, este artículo tiene como objetivo analizar el impacto ético y bioético de la urgencia de la investigación e identificar la vulnerabilidad de las personas en tiempos de pandemia. Se concluye que la integridad ética y la observancia de los principios bioéticos son centrales en la investigación clínica, y que, a pesar de la necesidad de agilizar los procesos de investigación, se deben cumplir todas las etapas. Además, se debe considerar la vulnerabilidad de los participantes desde la perspectiva de la bioética de protección.

**Palabras clave:** Bioética. Revisión de integridad científica. Infecciones por coronavirus. Vulnerabilidad en salud.

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Diseases have always threatened humanity. For centuries people have tried to understand their causes, transmission and prevention process, aiming at establishing treatments and mainly, to cure them, consolidating the current empirical process. Today, it is recognized that a research must follow the scientific method (building hypotheses, designing experiments, analyzing data and communicating results [1]), in addition to adapting to ethical and bioethical principles, in order to validate the results. However, even after centuries of discoveries, Nature constantly brings surprises related to new lethal zoonotic viruses.

On January 30rd, 2020, the World Health Organization (WHO) declared an international public health emergency due to the spread of human infection caused by the new coronavirus [2] (Covid-19 variant), caused by Sars-CoV-2. The virus was first identified in Wuhan, Hubei province, China, in early December 2019, and on March 11th, 2020, the WHO declared a pandemic [3].

Due to this new scenario, the scientific community, governments, and companies had to adopt emergency measures to accelerate studies to find solutions to stop the disease. In six months of pandemic, several articles have been published, even without peer review, which puts its integrity under scrutiny. Faced with this problem, this article analyzes the ethical and bioethical impacts of urgent studies, and tries to identify the vulnerability of individuals in times of pandemic, based on the literature and legislation on the subject.

## Clinical research: concepts and regulations

Clinical studies are currently organized according to the scientific process (idealization, execution and dissemination of results) based on valuing the human person and protecting fundamental rights. Accordingly, this type of investigation was structured to safeguard, through regulations and institutions, *respect for strict ethical standards, both national and international, ensuring that participants are not exposed to risks, also securing that the generated data in the research are valid and accurate* [4]. To understand this process of ethical investigation and scientific integrity, it is first necessary to define the concept of clinical research and characterize its stages, as well as the norms and agents involved.

According to Wong and Schulman, *a clinical research directly involves a person, group of people or material of human origin (such as tissue or specimens, or cognition), with a researcher, who directly interacts with human participants or collects privately identifiable information* [5]. It may focus on the patient, through epidemiological and behavioral studies or health outcomes and services. Patient-centered health care addresses diseases, therapeutic interventions, clinical trials and the development of biotechnologies, and would be the most vulnerable form of experimental exercise, since they are based on human research subjects.

When dealing with clinical experimentation, Bigelow states that *a clinical study is an attempt to learn more about a disease and its manifestations, causes or outcomes* [6]. Such studies may be small, describing only a few important cases, or include thousands of patients, involving the creation of more sophisticated databases and statistical methods. Retrospective studies collect and analyze information from past events, and the prospective ones identify a population of participants (cohort) and monitor it for a specific period [1].

The Brazilian Health Regulatory Agency (Anvisa) defines clinical research *as studies carried out with humans to measure the safety and efficacy parameters of new drugs, being essential for the availability of new therapeutic alternatives on the market* [7]. In such cases, research follows consecutive stages. The initial one is called "pre-clinical" and performed in laboratories and with experimental animals to analyze safety aspects before the application of the drug to humans. Subsequently, the research moves to the clinical stage, divided into four stages [8].

Initially, the drug is tested for the first time in humans, usually in healthy individuals. Different doses and routes of administration are evaluated and interaction tests with other drugs are carried out to establish a preliminary evolution of safety and the pharmacokinetic profile. Generally, from 20 to 100 individuals participate in this stage.

The second step (pilot therapeutic study) corresponds to the first controlled studies, in which individuals who have the disease or condition under examination are tested in order to begin the evaluation of the effectiveness of the new drug or procedure, as well as to confirm the safety, bioavailability and bioequivalence of different formulations [8]. This stage generally comprises 100 to 300 participants, and different dosages and the analysis of other indications of the drug [9].

After completing the pilot study, in the third stage, large multinational and multicenter studies follow 300 to 3000 volunteer patients [9] for a longer period. Usually in this stage the studied procedure is compared to a standard therapy, that is, researchers use drugs or treatments already approved and available to verify the efficacy, tolerability and safety of the new drug. The volunteer may receive the new treatment, the standard or placebo. This stage includes a randomized study [8] that compares therapies and establish the superiority of one over another.

Finally, the fourth stage regards the approval of the drug or procedure and its availability on the market. Follow-up tests are carried out to gather additional information on safety and efficacy, also defining unknown or incompletely qualified side effects and associated risk factors. This last step is known as "pharmacovigilance" or "post-marketing" and must follow the same ethical and scientific standards applied to the previous stages [8]. The pre-clinical stage has an indefinite duration; the first stage lasts a few months, the second up to two years, and the third takes from one to four years [9].

Currently, the entire clinical research process is governed by rules that provide for ethical duties. In Brazil, the resolution of the National Health Council (CNS) 466/2012 [10] is the main regulatory guideline, and focuses on human dignity and the protection of the participants. Its objective is to ensure the rights and duties of these individuals, the scientific community and the State [8]. The principles that underlie it come from several international human rights treaties, codes and declarations [11-18].

CNS Resolution 466/2012 [10] determines that all research involving human beings must be analyzed by research ethics committees (CEP, in Brazil) coordinated by the National Research Ethics Commission (Conep). Thus, we have the following main agencies in Brazil to guide ethical and regulatory aspects of clinical research in Brazil: Anvisa, Conep and CEP [8].

In this context, Anvisa analyzes and approves the Drug Clinical Drug Development Dossier and the Specific Dossier for Clinical Trial for each protocol. The agency controls the import of experimental drugs and research materials and records any products resulting from the protocols. On the other hand, Conep evaluates ethical aspects of research and coordinates CEP, which, in turn, evaluate the studies of the research centers. They are *interdisciplinary and independent committees with public relevance and consultative, deliberative and educational nature* [19] that defend the integrity and dignity of research participants and guarantee ethical standards.

All these regulations, standards and institutions are primarily related to bioethics and scientific integrity. The latter also includes combating practices such as falsification, fabrication, plagiarism and inadequate tutoring relationship in research [20] to ensure the credibility of results – an ethical principle that is different from guaranteeing the rights of participants, but equally important in the validation process.

These institutions are responsible for guaranteeing the integrity of the research, and the funding agencies have a central role in the formulation and establishment of policies. In 2011, a set of ethical guidelines was released by the Brazilian National Council for Scientific and Technological Development (CNPq) [21], and the São Paulo Research Foundation (Fapesp) published a Code of Good Scientific Practice [22] that provides for the establishment of bodies and processes to verify scientific integrity in research institutions linked to the foundation.

Clinical research usually has a long development time. However, in the context of the emergency imposed by Covid-19, the main challenge has been to quickly fulfill all stages of this type of study to solve the problem and guide public policies. In this sense, emergency measures were created to speed up regular processes, and these changes may affect ethical principles and integrity.

## Impacts of the Covid-19 pandemic on clinical research

In the challenging scenario imposed, exceptional measures were necessary to meet the demand of the population and the scientific community, in the process of ensuring ethical principles and integrity and in the publication of clinical research results. The exceptional nature of the situation motivated researchers to undertake great efforts to find therapeutic and pharmacological solutions to contain the virus.

The first major change occurred in the publication of the results: since the beginning of the pandemic, scientific journals have been providing free access to content related to the new coronavirus to expand access to information and support the work of researchers, managers and engaged professionals with the global health emergency [23]. The American

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Society for Microbiology, Elsevier, Springer Nature, Johns Hopkins University School of Medicine and the journals *Science*, *New England Journal of Medicine*, *The Lancet*, and the Brazilian journals *Cadernos de Saúde Pública*, *Revista Brasileira de Epidemiologia*, *Ciência e Saúde Coletiva*, *Revista Brasileira de Saúde Ocupacional*, *Revista do Sistema Único de Saúde do Brasil*, *Vigilância Sanitária em Debate* and *Saúde e Sociedade*, among others, offered free access to their content on the Internet [24].

Some journals adopted the fast-tracking process, a set of procedures to speed up editorial evaluation, peer review and publication of scientific articles related to the pandemic. Others opted for the preprint publication model: articles not reviewed by other researchers, and therefore without formal certification. In this model, the manuscript is deposited by the author on a specific server about Covid-19 and made available for public access [25].

As for the ethical principles and integrity, Conep established special processing steps, in accordance with the provisions of item IX.10 of the CNS Resolution 466/2012 [10]. The exceptional nature of this procedure was decided in a plenary meeting and will last as long as WHO maintains the global state of emergency. With this, research protocols on Covid-19 must be sent directly to Conep for consideration, without analysis by CEP [26].

In addition, on April 22, Anvisa published Technical Note 14/2020 [27] to guide sponsors, research centers and researchers involved in clinical trials authorized by the agency and bioequivalence studies. The note informs the creation of the Committee for the Evaluation of Clinical Studies, Registration and Post-Registration of drugs for the prevention or treatment of Covid-19 and establishes guidelines for ongoing clinical trials. It also disclosed specific information regarding bioequivalence centers and data to be sent in the Annual Report of the Clinical Trial and Final Study Reports on Bioequivalence affected by the measures to combat the new virus, since universities and research centers had to stop studies in progress to reallocate resources, equipment and scientific labor [28].

In addition, Conep created a weekly report to update the population on the evolution and ethical analysis of research protocols involving human beings. According to Report 32, until July 11, 2020, *565 scientific research protocols were approved, of which 423 were observational and 142 were interventional or experimental* [29]. The report [30] also presents an infographic detailing various drugs, vaccines and devices being evaluated by 142 approved experimental/interventional studies. It also indicates that 44 Brazilian institutions have proposed clinical trials, and that 69.7% of the approved protocols came from public entities, with a sample size ranging from 1 to 8,870 participants. In total, the research had 58,311 participants, and more than 420 observational studies are in progress [30].

Researchers are working on an emergency basis to ascertain the safety and efficacy of drugs or treatments within the parameters of toxicity, potency, dosage, weather conditions and the conduct of clinical studies. The collected data allow verifying if the studies follow rigorous national and international ethical standards, so health professionals can advance based on health protection with a solid base of scientific and ethical integrity, with valid observations and concrete documentation results. For this, researchers must adopt good clinical practices that meet the interests of all those involved, institutions, researchers and participants, ensuring their rights, safety and well-being [8].

During a pandemic, health managers and public authorities need to take emergency measures to combat the disease, based on available scientific evidence. However, controversial studies with very small samples, low efficacy and limited data should be avoided, since this type of research cannot support public policies, given the risk of adverse effects and intoxication that can further aggravate the situation.

Political pressures and uncertainties generated by the crisis can induce doctors and researchers to inadequate biases, damaging the integrity of the research and leading to the dissemination of premature results, with recommendations based on improper conclusions and limited data. Such studies go against the scientific method and serve just to confuse and, in the worst case, to deceive, especially in a tense moment, when help is essential [31]. To curb such misunderstandings, it is essential to establish limits and always observe the scientific method, regardless of the global health emergency.

Such restrictions are established by the aforementioned legislation and must always be observed in research involving human beings, especially in the context of a pandemic. Researchers and health professionals must consider article 4 of the *Universal Declaration on Bioethics and Human Rights* [16], according to which decisions and practices must be evaluated to guarantee the maximum benefit and minimum damage to patients, research subjects and other individuals who may be affected.

Item III.1 of the CNS Resolution 466/2012 [10] reinforces this understanding, recommending that research involving human beings should meet pertinent ethical principles, such as respect for the patient's dignity and autonomy, recognizing their vulnerability, weighing risks and benefits, avoiding predictable damage and highlighting the social relevance of the research. In addition, items III.2 and III.3 establish guidelines to adapt the research to scientific principles, such as grounding in facts, predominance of the expected benefits over predictable risks and discomforts, adequate methods to answer the studied questions, informed consent, among others [10].

Faced with the uncertainties caused by the pandemic, physicians and researchers must have an ethical posture, safeguarding integrity and preventing scientific misconduct, such as plagiarism, fabrication or falsification of data. In the context of bioethics, we must emphasize the principles of non-maleficence, beneficence and respect for autonomy. It is also necessary to reflect in the midst of a crisis about biases that can influence thinking and critically evaluate evidence, to then decide how to treat patients. Anecdotal observations should be limited to the construction of hypotheses for trials that can be conducted with clinical equipment [32].

## Vulnerability in pandemic times

As already discussed in this article, the construction of knowledge in clinical studies is based on the ideal historically related to the respect for human beings, allowing an understanding of the central role of bioethics in the adequacy of research and in the validation of results. CNS Resolution 466/2012 [10], the main guideline for this type of research in Brazil, incorporates bioethical references – non-maleficence, beneficence, justice, autonomy and equity – in its preliminary provisions. Thus, agencies and institutions are urged to guarantee the basic rights of individuals who participate in clinical research.

The bioethical recommendation of guaranteeing fundamental rights raises the question of the vulnerability of clinical research participants. Resolution 466/2012 covers the topic, and in its item II.25 defines "vulnerability" as the *state of people or groups that, for whatever reasons or motives, have their capacity of self-determination reduced or impeded, or prevented from opposing resistance* [10]. On the other hand, item III.1, among other principles, limits the research to the possibility of participants expressing their willingness to contribute to the study or not.

However, we must highlight the complexity of the concept. Dallari [8] states that patients exposed to specific conditions are subject to a higher degree of vulnerability – such as children and the elderly, for example. According to the author, *the disease, by itself, distresses, weakens and even humiliates, making the research participant a vulnerable subject* [33]. Accordingly, vulnerability can be understood as an inherent state of risk, which ends up unbalancing the relationship of free consent presupposed in clinical research, requiring the protection of the participants.

In the context of Covid-19, emergency decision making for treatments and solutions ends up creating situations of uncertainty and anxiety that extends the concept of vulnerability to all patients. On the other hand, the great amount of clinical research and processes aiming at more efficient approvals and wider and faster dissemination of the results, as evidenced previously, generate issues about the basic rights of individuals. In the legal sphere, several situations force us to reflect *on the purposes of the Law, in particular, and its function of guaranteeing the protection of the vulnerable, in resistance to political, market pressures and individualist attitudes* [34].

Coping strategies, and in particular clinical research, point to a degree of uncertainty related to the information available. There is much to learn about the Sars-CoV-2 virus, particularly in terms of its transmissibility, virulence potential, spectrum of clinical manifestation, treatments and cure with proven scientific evidence. The speed of the virus spreading has been one of the major concerns of professionals before the scarcity of resources and deficient hospital structure, which can lead to the collapse of the health system.

This scenario provokes instability and insecurity in the population, further jeopardizing the members of the group of risk – elderly over 70 years old, people with chronic diseases or impaired immune systems, HIV positive, transplanted people [35] – and populations who are already in a social vulnerable situation (such as deprived communities), as well as participants of clinical research, also vulnerable in a pandemic crisis.

To cope with the problem, the Brazilian Ministry of Health created the National Contingency Plan for Human Infection with the new Covid-19,

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which points out that *facts and knowledge about the new coronavirus* (…) *available are still limited. There are many uncertainties regarding the mode of transmission and the possible reservoirs. The lethality, mortality and transmissibility rates are not definitive, being underestimated or overestimated. Epidemiological and clinical evidence is still being described and the history of this disease is being constructed.* (…) *The risk will be periodically evaluated and reviewed, considering the development of scientific knowledge and evolving situation, to ensure the response level and the adoption of corresponding measures* [36].

Regulatory and health agencies can ensure public policies to safeguard the interests of vulnerable people through the bioethics of protection or "ethics of protection," which is based on reflections on health justice in situations of scarcity [37]. Considering this aspect of bioethics, it is possible to seek wide-ranging solutions, in order to reach people in situations of social vulnerability, creating more effective sanitary measures to combat Covid-19.

On the other hand, it is also possible, by applying the bioethics of protection, to ascertain the morality of clinical research with human beings during a pandemic outbreak. The research participants must have their rights guaranteed: the informed consent form, physical integrity, immediate and integral assistance, and especially human dignity. Even in a global emergency situation, subjects cannot be considered guinea pigs for the benefit of the community.

## Final considerations

Empirical scientific knowledge is based on experimentation, which must follow the scientific method to have its validly proven. In addition, on must follow ethical standards of respect for the basic rights of research participants, who are considered vulnerable, and to avoid bad practices that can affect the credibility of the results. New drugs and treatments are developed in clinical research that aim to prove the greater efficiency of the new therapeutics in comparison to the existing ones, as well as to delimit parameters of toxicity, potency and dosage.

The Covid-19 pandemic had a profound impact on research, prompting the scientific community to make great efforts to contain the disease. Universities and research centers were mobilized, reallocating resources, equipment and labor for studies on the new coronavirus. As a result, the number of clinical trials increased, and the research councils had to adopt emergency measures to prioritize the ethical evaluation of these studies.

In view of the uncertainties about transmission, treatment and virulence potential, the committees allowed researchers to publish scientific articles without peer review, the so-called "preprints." On the one hand they may contribute to the information available, but on the other can lead to misinterpretations and inadequate applications. Thus, results are anticipated and used with a "definitive solution" aura in a context of general anxiety, in which the condition of vulnerability increases. For this reason, it is essential to follow strict standards before releasing results that can generate false hopes and lead to hasty decisions, which could aggravate the problem.

To deal with so many uncertainties, and to ensure robust and reliable results we must seek the centrality of ethical and bioethical principles applicable to research. Regarding the morality of clinical studies with human beings during the pandemic, we conclude that the bioethics of protection must be applied, since research participants who are under a situation of vulnerability must have guaranteed the right to informative self-determination, physical integrity with immediate and comprehensive assistance and human dignity.

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