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Research Ethics Challenges in Pandemic Korea and Their Implications for the Revised 2024 Declaration of Helsinki

Running title: Pandemic and Implications of the Revised 2024 Declaration of Helsinki

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ABSTRACT

Background: The pandemic significantly impacted research ethics, vastly magnifying existing challenges. This study examines challenges for research ethics in Korea during coronavirus disease 2019 (COVID-19) and their implications for the 2024 revised Declaration of Helsinki.

Methods: As a literature search method, we applied the scoping review protocol using six databases, search keywords related to research ethics and COVID-19, then analyzed key themes against the revised Helsinki Declaration.

Results: We reviewed the literature on research ethics during the COVID-19 pandemic in the Republic of Korea, identifying ten key themes: 1) participant safety; 2) national governance; 3) community engagement; 4) global cooperation; 5) reliable research; 6) rapid Institutional Review Board reviews; 7) consent adaptation; 8) fair inclusion of vulnerable groups; 9) ethics of human challenge trials; and 10) use of human materials without consent. The revised Helsinki Declaration of 2024 newly introduces: 1) ethical principles in public health emergencies; 2) meaningful community engagement; 3) scientific rigor; and the Declaration reframes 4) addressing vulnerability; and 5) informed consent for biological materials.

Conclusion: By analyzing the relevance and implications of the challenges identified in this literature review in relation to the revisions made to the Declaration of Helsinki in 2024, we demonstrate that the updated Declaration addresses most of the ethical challenges posed by research in pandemic Korea. This paper highlights that the 2024 revision underscores the significance of research ethics during pandemic situations and proposes approaches to enhance the research environment and ecosystem in the 21st century post-pandemic.

Keywords: Research Ethics; Research Integrity; COVID-19; Republic of Korea; Declaration of Helsinki

INTRODUCTION

In October 2024, the World Medical Association (WMA) issued a revised version of the Declaration of Helsinki, marking its 60th anniversary.[1] Initially adopted in 1964 in Helsinki, Finland, this foundational document has guided medical research ethics for six decades, shaping international guidelines and national regulations in countries such as Republic of Korea, the United States, Japan, and members of the European Union. As a "living document" built on a solid ethical foundation, the Declaration has consistently evolved to address contemporary issues in medical research and bioethics.[2]

The 2024 revision reflects significant advancements in bioethics over the past decade, incorporating new provisions to address the evolving landscape of medical practice and research. The revision initiated during the coronavirus disease 2019 (COVID-19) pandemic was shaped not only by the unprecedented ethical challenges of the time but also by the broader need to address advancements and evolving issues in research ethics. This comprehensive and transparent process spanned 30 months. Initiated in April 2022, the revision involved a working group of experts from 18 countries, coordinated by the American Medical Association and informed by global feedback. The updated Declaration seeks to reaffirm its foundational principles while strengthening its applicability to modern research contexts.

The COVID-19 pandemic underscored the importance of revisiting and adapting research ethics to address emerging challenges. The pandemic not only caused significant societal and public health crises but also tested the flexibility of ethical principles in medical research. Issues such as ensuring participant safety, expediting Institutional Review Board (IRB) reviews, protecting vulnerable populations, fostering community collaboration, and addressing the ethical use of data and biological materials became critical focal points. In South Korea, these discussions encapsulated advancements in ethical principles while highlighting areas that required further development.

This paper examines the extent to which the 2024 revision of the Declaration of Helsinki reflects the ethical challenges that emerged during the COVID-19 pandemic, with a particular focus on Korea. By analyzing Korea’s research ethics discussions during the pandemic and their reflection in the revised Declaration of Helsinki, this study aimed to provide a deeper understanding of how global ethical guidelines can adapt to contemporary challenges. It underscores the importance of preparing research environments for future pandemics by integrating lessons learned into both national and international

ethical frameworks. By analyzing the relevance of these revisions to the pandemic experience, the study aims to offer practical insights for preparing research environments to address future public health emergencies. It also seeks to contribute to ongoing discussions about fostering a resilient and ethically sound research ecosystem in the post-pandemic era.

An analysis of papers published during the pandemic reveals that the discussions on challenges in research ethics in Korea are significantly reflected in the revised Declaration of Helsinki 2024.[3] This updated declaration preserves many principles from its last version in 2013, underscoring the enduring importance of core ethical principles in medical research involving human participation. The newly introduced or modified provisions in 2024 reflect the evolving landscape of research environments and ethics over the past decade, particularly addressing challenges encountered during the COVID-19 pandemic that began in 2019. This paper aimed to examine these research ethics challenges in Korea during the pandemic through a literature review and analyze their implications in relation to the revised Declaration of Helsinki 2024.

The coronavirus pandemic presented the most challenging global crisis since World War II.[4] To effectively cope with the era of pandemics, the global community has pursued developing fast-reaction systems designed to respond more quickly to emerging medical threats. Fast reaction systems, which include accelerated research, are likely to encounter significant ethics and integrity challenges. In 2022, a European Union funded project—**Pr**o-activ**e** **Pa**ndemic C**r**isis **E**thics an**d** Integrity Framework (**PREPARED**)—started to develop a research ethics and integrity framework, to safeguard key ethical values, whilst supporting a rapid and effective research response to crises. Consisting of various stakeholders including researchers from Europe, Africa, Asia, North America and Australia, PREPARED conducted reviews in nine languages (Korean, English, French, German, Hindi, Chinese, Russian, Japanese, and Spanish) to identify emerging research ethics and integrity challenges in the context of sudden, unexpected global crises. As a result of PREPARED team's analyses, the responses of the Korean government to research ethics,[5] as well as scoping reviews from Germany and China,[6,7] have already been published.

As a part of this effort, the present authors conducted a literature review in Korea with the following research questions: 1) What research ethics and integrity challenges are foremost and/or

peculiar to research in a sudden and unexpected crisis? and 2)What is the guidance for addressing research ethics and integrity challenges associated with research in a sudden and unexpected crisis? The purpose of this review was to provide a literature-based response to the above two questions, specifically focusing on the case of the COVID-19 pandemic. It was based on literature generated in the Republic of Korea (South Korea) and aimed to identify challenges faced by actors in the research ecosystem during the pandemic.

METHODS

We applied the scoping review protocol by Tricco et al.[8]. Six databases (2 international, 4 Korean) were used to search for the relevant keywords. The international databases were PubMed and Scopus. The Korean databases were Korean studies Information Service System (KISS), Research Information Sharing Service (RISS), Korea Citation Index (KCI), and Journal of Korean Association of IRB database (JKAIRB). For the international databases, search keywords were constructed as [("research ethics" or "research integrity" or "research governance" or "scientific integrity") AND (COVID-19 or COVID or pandemic) AND Korea]. For the Korean databases, the same search keywords as well as their Korean equivalents were used. The search focused on papers published up to March 2023, which was the research period (Fig. 1).

Search results from each database were screened for eligibility criteria as well as the relevance of content. Eligibility criteria included 4 inclusion criteria and 7 exclusion criteria.

Inclusion criteria:

1) Papers on research ethics or research integrity related to COVID-19 or pandemics,
2) Articles written about Korea, or about what happened in Korea,
3) Written in English or in Korean,
4) Published after 2020

Exclusion criteria:

1) Papers that did not target Korea as a subject;
2) Non-research papers on Korea's response to COVID-19 (e.g., policy papers);
3) Papers on COVID-19 research in Korea that did not address research ethics;
4) Papers on governance related to COVID-19 in Korea that did not address research ethics;
5) Papers on various topics related to COVID-19 in Korea, other than research ethics;
6) Papers written in languages other than Korean or English;
7) Papers with inappropriate content.

Overall, 34 papers were selected from which 13 duplicates were removed. Finally, 21 papers remained for the analysis. We compiled a list of the key ideas and concepts of research addressed in each paper.

Subsequently, we grouped them based on their similarities. These similar arguments were then organized into main themes. After that, we reviewed implications of the themes identified in this paper in relation to the newly revised Declaration of Helsinki 2024. To examine whether the challenges of research ethics during the COVID-19 pandemic in Korea were reflected in the 2024 revision of the Helsinki Declaration, the authors conducted a study focusing on the newly introduced or heavily revised sections of the Declaration.

RESULTS

Prioritization of the safety of research participants

The COVID-19 pandemic has serious implications for individuals who participate in existing, non-COVID clinical trials as patients. Academic papers argued that the safety of study participants should be the top priority in the COVID-19 situation.[9-12] Korea is one of the leading countries conducting clinical trials, with a growing number of trials for serious and rare diseases, especially anticancer agents.[10] The COVID-19 pandemic can have serious consequences for clinical trial participants with severe illnesses. In particular, patients with severe illnesses—who are participating in clinical trials to develop new treatments in the absence of effective therapies—may have very poor outcomes, including death, if they contract COVID-19. In such cases, the decision to suspend or continue clinical trials should be made by considering the extent of the COVID-19 outbreak in the region where the clinical trial was being conducted and the results of risk-benefit assessments associated with clinical trial participation. The COVID-19 pandemic made it difficult for patients to continue in non-COVID clinical trials, which could compromise their safety, as alternative treatments was not be available. It is important to ensure that patients who were receiving investigational drugs could continue to access them through ongoing clinical trials. If the trial was to continue, measures to prevent COVID-19 infection should be taken and ways to minimize hospital visits, such as changing the clinical trial plan, utilizing drug delivery, and conducting efficacy and safety assessments online or by phone, should be considered.

Efficient and effective national research governance for crisis response

An academic paper in the early phase of the pandemic argued that ethical preparedness was necessary for pandemic research.[13] The global pandemic of unprecedented scale and scope constituted a crisis that had to be managed at the national level, necessitating a concerted effort in research and development on the part of nations to effectively address the challenge. In the early stages, it was imperative to characterize the nature of the infectious disease and develop diagnostic methods, with subsequent utilization of research findings for infectious disease control. National and local communities, research institutions, research ethics governance officials, ethicists, and members of

research ethics committees/IRBs should first examine which research projects can best address the global crisis, considering ethical issues, including protection of research participants, and whether the research ultimately helps the local community.

The establishment of research governance structures at the national level is deemed crucial for future pandemics and disaster situations in the aftermath of the COVID-19 pandemic, as emphasized in various academic papers.[12-14] For Korea, these papers recommended the establishment of a Central IRB and the Clinical Trial Safety Support Institution at the national level through the revision of the Pharmaceutical Affairs Act.[15] Furthermore, the papers provided a comprehensive summary of the contents and significance of the legislation that enables prompt research and development and approval by various national agencies and experts during crisis situations.[16-18]

Community engagement in research

Developing community engagement networks in research was emphasized as a critical component of emergency preparedness.[13,14] To ensure sensitivity to the local realities, needs, values and culture, researchers, research institutions, and IRBs should engage the community at all possible stages of the research process. They should be involved in decision-making processes related to research design, implementation, and evaluation. While adhering to ethical requirements that respect human rights and protect personal information, sharing information generated during research with those involved in pandemic response efforts should maintain an effective and mutually beneficial balance between research and response.

Global solidarity and cooperation for research to respond to the pandemic

During the early stages of the COVID-19 pandemic, academic papers called for global solidarity and cooperation to urgently research and develop safe and effective vaccines to end the pandemic.[13,14] Written in Korean, their primary audience was Korean regulators, researchers, and academic communities. Such global solidarity and cooperation were argued to be ethical imperatives. Above all, these calls emphasized the need for swift, accurate, and transparent sharing of information and communication regarding the new viral disease. Policy makers and regulatory agencies were

encouraged to harmonize regulatory frameworks, while industry and research institutions were urged to accelerate research on therapies and vaccines by sharing data through research collaborations.

In times of international public health crises, transparency is crucial, and the dissemination of accurate information enables countries to take necessary measures. Scientific journals in Korea made their COVID-19-related publications freely available to facilitate access. In Korean medical academic journals, papers related to COVID-19 were promptly peer-reviewed and published—on average—within a week of submission.[19] The international community was called upon to share detailed scientific information in real-time about the viral disease's transmission patterns, incubation periods, pathophysiology, human immune responses, origins, genetics, and mutations. Joint efforts and information sharing among the global community were deemed essential to advance knowledge in all these areas and develop various treatment and prevention measures.

Striving for reliable research and avoiding research waste

In the early phase of the pandemic, a Korean paper addressed a pressing need for implementation of effective research for development of treatments and vaccines for COVID-19.[13] Within a few months of the emergence of COVID-19 as a global threat, research into treatments and clinical trials proliferated. These studies were often conducted at national or regional levels. Without global coordination, there was a risk of serious ethical and integrity issues arising from the production of inaccurate information in a short time frame. Uncoordinated small-scale studies with inadequate statistical power may be conducted in multiple locations, and patients may be enrolled in multiple clinical trials, which are uninformative. Additionally, the burden on healthcare systems caused by the surge in COVID-19 patients may result in delays in conducting clinical trials with a sufficient sample size. Unnecessary duplication of research efforts and weak research with insufficient statistical power should be avoided, and the activities of research teams could be internationally coordinated to align with global response efforts. As such, during the pandemic period in Korea, there was a call to strive for research that produces reliable and valid results, and to avoid wasting research efforts.

Rapid and thorough IRB review for crisis response

In scholarly literature pertaining to ethics in pandemic research in Korea, a consistent theme is the urgent need for ethics considerations in the research and development.[9,12,14,20] These papers emphasize that the safety of research participants and the maintenance of scientific and ethical standards in clinical research must not be compromised even during a pandemic. The independent and competent review by IRBs is crucial in protecting the safety and rights of research participants. As such, a prompt and rigorous IRB review is paramount to effective crisis response. Responding to the pandemic emergency, scholarly works have emphasized the importance of having in place research review capabilities and structures that prioritize expertise, efficiency, and expediency, to prevent ethical review procedures from delaying research processes. In particular, with the unprecedented scale and international cooperation involved in large-scale clinical trials, which may involve multiple institutions within Korea, it has been suggested that a single institution's IRB should be responsible for reviewing multi-institutional research projects.[13]

Adaptation of consent for research in pandemic crisis

In the context of pandemics, obtaining proper informed consent can be challenging due to various obstacles and difficulties. Nevertheless, all authors of related papers agree that obtaining consent is fundamental to ethical research. They argue that unless the conditions for consent exemptions are met, consent based on personalized information from research participants must be obtained.[10-12,14,21] Due to the difficulty of obtaining consent through face-to-face explanations for patients who are quarantined and undergoing treatment for COVID-19, several alternatives have been proposed, including telephone or video explanations, or consent from a legal representative. In cases where obtaining and storing paper consent forms from COVID-19 patients poses a risk of infection transmission, it has been suggested to capture photographs of the consent forms and transmit them via email or social networks for digital storage.

Fair and responsible inclusion of individuals or groups with vulnerability

During the COVID-19 pandemic, research ethics papers published in Korea have emphasized the need for a fundamental rethinking of the ethics surrounding vulnerable groups and individuals, as well

as the fair selection of research participants. While it is crucial for pandemic research to acknowledge the heightened vulnerabilities of those adversely affected, it is unacceptable to exclude individuals or groups solely based on their vulnerabilities without scientific or ethical justification.[12] Proactively excluding these populations can impede valuable research efforts, potentially increasing their vulnerability to harm rather than providing protection.

For instance, many pandemic research projects have shifted to remote methodologies, utilizing online or mobile platforms. This shift may inadvertently exclude individuals or groups who lack familiarity with digital technology, such as certain people with disabilities or older adults. Consequently, researchers should implement additional measures to enhance accessibility for those who might otherwise be marginalized in the research process.[12] Ethical pandemic research entails community involvement and inclusive decision-making, necessitating all reasonable steps to ensure the participation of all stakeholders, including vulnerable and marginalized populations. Two example groups that were discussed in more detail are soldiers and pregnant women, as research participants.[22-24] Soldiers are considered vulnerable research participants because voluntary participation in studies is often difficult due to concerns about potential pressure from higher-ranking officials. However, excluding soldiers from research solely based on their vulnerability is unjustified, as argued in these studies. In particular, soldiers may face heightened vulnerability during the COVID-19 pandemic due to shared living arrangements and training activities. Therefore, research should be conducted to develop appropriate physical and psychological coping mechanisms for soldiers in the face of COVID-19, as well as to develop vaccines and treatments. To address the vulnerability of soldiers, which is rooted in the hierarchical order of military obedience, IRB review and consent procedures should be specially designed to ensure autonomy and involve external monitoring. Excluding soldiers from research based on vulnerability could inadvertently reinforce their vulnerability.

One paper addresses the ethical implications of clinical research involving pregnant women during the COVID-19 pandemic.[25] It highlights the historical exclusion of this demographic as vulnerable participants in various epidemics, including novel influenza, Ebola virus disease, Zika virus, severe acute respiratory syndrome, and tropical malaria. The authors contend that pregnant women should not be classified solely as vulnerable research participants; rather, they should be

recognized as a 'scientifically complex group.' The inherent 'scientific complexity' of pregnancy should not justify the unjust exclusion of pregnant women from clinical research over decades. Instead, it should be viewed as an opportunity to generate valuable medical knowledge that could benefit both mothers and fetuses through the responsible inclusion of this crucial population in research.

After demonstrating the ethical justification of including pregnant women in clinical research by applying the principles of non-maleficence and justice, the authors argue that it is an ethical obligation to include pregnant women in COVID-19 clinical research. Despite the numerous challenges posed by clinical research on pregnant women, the potential for advancing medical knowledge and preparing for future epidemics makes addressing these challenges imperative. The Korean government, academia, and the private sector should increase research funding and provide technical support, such as developing protocols to ensure the safe participation of pregnant women in research. The knowledge gained from studying infectious diseases in pregnant women, including their immunological changes affecting susceptibility to infection, will be invaluable for responding to current and future epidemics and optimizing prevention and treatment of these diseases.

Ethics of human challenge trials

The use of human challenge trials, where participants are deliberately exposed to pathogens to evaluate vaccine efficacy, has gained attention as a potential response to COVID-19. In Korea, four academic papers have been published on this topic.[13,21,26,27] These studies examined the risks, benefits, and ethical considerations of participant consent. They compared the criteria proposed by the World Health Organization and western scholars, and analyzed historical cases of human challenge trials for diseases like dengue fever, cholera, and the Zika virus.

To be ethically justifiable for COVID-19, human challenge trials must demonstrate significant social value and adhere to ethical standards that ensure participant safety. This includes securing treatments, producing attenuated strains of pathogens, or implementing safety measures for equivalent pathogens.[26,27] Currently, facilities and logistical capacity for human challenge trials are not available in Korea. Therefore, ethical discussions should focus on building long-term pandemic

response capacity rather than solely on shortening vaccine development timelines. As infectious diseases are predicted to continue spreading globally beyond COVID-19, human challenge trials should be considered as one option for long-term scientific and ethical pandemic responses, according to Korean authors.

Use of human material obtained for pandemic response without consent for research

In addition to research governance and consent issues, the COVID-19 pandemic also raised critical questions regarding the fair distribution of scarce medical resources such as vaccines. Ethical discussions on vaccine allocation emphasized efficiency, equity, and fairness as guiding principles, highlighting the broader social context in which research ethics debates were situated in Korea during the pandemic.[28]

One study has raised concerns regarding the use of data or samples obtained during the pandemic response without appropriate IRB approval or consent from research participants.[29] While certain public health surveillance activities must be conducted by the government without the consent of the involved parties to fulfill its obligations for infectious disease control, the lack of a clear distinction between research and public health surveillance activities can compromise the fundamental principle of consent in research ethics. Particularly in the early stages of the pandemic, securing samples from COVID-19 patients was critical for a prompt response. However, there were instances where samples were collected without obtaining informed consent due to the difficulty of obtaining timely IRB-approved consent. While the Bioethics and Safety Act provides a legal basis for exempting research conducted by the government or public institutions from IRB review, IRB approval and consent are still required for sample collection for research purposes. Secondary use consent must also be obtained in accordance with the law.[14] For human-derived materials that were collected without consent initially due to pandemic response needs, an alternative proposal is suggested, which involves IRB review and anonymization to permit secondary use.[29]

Table 1 summarizes the 10 main research ethics challenges and associated recommendations identified in the Korean literature for the COVID-19 pandemic.

The following section examines which parts of the revised Declaration of Helsinki might respond to

the 10 research ethics challenges identified in Korea during the COVID-19 pandemic.

DISCUSSION

The revision of the Declaration of Helsinki was a critical response to evolving ethical challenges in medical research. The WMA Council decided in April 2022 to revise the 2013 version of the Declaration. A working group with representation from 18 countries was formed to receive opinions and feedback from the global community.[30] After a 30-month revision process, the revised Declaration of Helsinki was adopted at the 75th WMA General Assembly held in Helsinki, Finland, on October 19, 2024. This 'living document' aims to respond to the changing research environment and embrace the developments of the past decade.[2] To ensure the legitimacy and transparency of the revision process, eight thematic meetings were held in various regions around the world, and public feedback was sought over two separate periods. In April 2022, when the decision was made to start the revision process, the world was still grappling with the COVID-19 pandemic. Hence, one would expect that the revision includes new elements relevant to pandemics.

To examine whether the challenges for research ethics during the COVID-19 pandemic as identified in Korean literature were reflected in the revised Declaration of Helsinki, the authors first extracted newly introduced or heavily revised sections in the 2024 revision and then compared those with the 10 challenge groups identified in Table 1.

Upholding ethical principles in public health emergencies

The revised Declaration of Helsinki in 2024 established a new provision relevant to emergencies with Article 8:

> "While new knowledge and interventions may be urgently needed during public health emergencies, it remains essential to uphold the ethical principles in this Declaration during such emergencies."[3]

Article 8 emphasizes—as a lesson learned from the COVID-19 pandemic—that public health emergencies do not reduce the importance of ethical principles in research.

Theme 10 from the Korean literature review is a match with the new article in the Declaration, as it provided a practical example, emphasizing that the principle of informed consent must be retained, even during emergencies.

Fostering meaningful engagement

The topic of meaningful engagement with research participants and their communities was never part of the Declaration of Helsinki before and it has made a very strong appearance in the Declaration in a significantly revised Article 6:

> "Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers should enable potential and enrolled participants and their communities to share their priorities and values; to participate in research design, implementation, and other relevant activities; and to engage in understanding and disseminating results."[3]

Theme 3 of our review, community engagement in research, is a full match with the revised Declaration. The ethical requirement to understand the needs and circumstances of communities that are involved in medical research should be a shared commitment among researchers, sponsors, and IRB members, according to the Korean literature reviewed above. Such needs have also been identified in other regions. For instance, based on COVID-19 experiences in Kenya, discussions on the ethical challenges in a global pandemic highlighted the need for meaningful community engagement with the researched communities.[31] This engagement seeks to foster more than just one-way trust in the research team; it strives to establish a genuine and respectful collaboration with communities before, during, and after the research process, as required.

Ensuring scientific rigor and avoiding research waste

Numerous medical studies were conducted to overcome COVID-19; however, many of these studies failed to yield valid results.[32] The revised Declaration of Helsinki responded to this challenge with an addition to Article 21:

> "Medical research involving human participants must have a scientifically sound and rigorous design and execution that are likely to produce reliable, valid, and valuable knowledge and avoid research waste."[3]

Concerns regarding the wastefulness of such research have been raised in Korea, and Theme 5, Striving for Reliable Research and Avoiding Research Waste, is a full match with the concern addressed in revised Article 21.

Addressing vulnerability: importance of inclusion and support

One of the most dramatic changes in the revised Declaration of Helsinki is related to vulnerability. Articles 19 and 20 were revised in full to read:

> "Some individuals, groups, and communities are in a situation of more vulnerability as research participants due to factors that may be fixed or contextual and dynamic, and thus are at greater risk of being wronged or incurring harm. When such individuals, groups, and communities have distinctive health needs, their exclusion from medical research can potentially perpetuate or exacerbate their disparities. Therefore, the harms of exclusion must be considered and weighed against any harms of inclusion. In order to be fairly and responsibly included in research, they should receive specifically considered support and protections."[3]

> "Medical research with individuals, groups, or communities in situations of particular vulnerability is only justified if it is responsive to their health needs and priorities and the individual, group, or community stands to benefit from the resulting knowledge, practices, or interventions. Researchers should only include those in situations of particular vulnerability when the research cannot be carried out in a less vulnerable group or community, or when excluding them would perpetuate or exacerbate their disparities."[3]

Two changes are apparent. First, the term 'vulnerable group' is no longer used, as it can be regarded as disrespectful and stigmatizing.[33] Instead, the revised version refers to 'situations of vulnerability'. Second, the fair and responsible inclusion of those in vulnerable situations is recommended rather than their exclusion from research.

The very awareness of the second issue has been pointed out several times in discussions

regarding research ethics challenges in Korea and is covered in Theme 8 of our review ("Fair and Responsible Inclusion of Individuals or Groups with Vulnerability"). Academic papers on research ethics widely discussed fair and responsible inclusion of individuals or groups who are in situations of vulnerability. This means that the categorical exclusion of, for instance, military personnel, pregnant women, the digitally vulnerable, the elderly, the disabled, etc. from research should be reconsidered in Korea.

Instead, special efforts and resources should be invested in including them in research. Several scholars globally also advocated for the inclusion of pregnant women in research for drug and vaccine development during the COVID-19 pandemic.[34-36] The new content in the 2024 revised Declaration of Helsinki emphasizes the necessity of providing tailored support and protections for fair and responsible inclusion in research, a principle that resonates deeply with the discussions held in Korea during the pandemic regarding the inclusion of individuals or groups facing vulnerability.[3]

Informed consent in research involving biological materials and data

The 2024 revised Declaration of Helsinki provides clear guidelines regarding consent for research involving human-derived materials or data as Article 32 was significantly expanded, also to cover secondary use of data:

> "Physicians or other qualified individuals must obtain free and informed consent from research participants for the collection, processing, storage, and foreseeable secondary use of biological material and identifiable or re-identifiable data."[3]

A research ethics committee is required to authorize the creation and oversee the continuous use of databases and biobanks. In situations where obtaining consent is not feasible, the Revised Declaration permits secondary research use of stored data or biological materials only after the careful evaluation and approval of a research ethics committee.

Theme 10 of our review deals with the difficulties of obtaining informed consent during public health emergencies and the recommendation that IRB review plus anonymization can lead to the authorization of secondary use. The issue of specimen collection for pandemic research leaves an ethical debate that may continue in the future. Currently, the Korean government can collect

information and specimens for pandemic response without individuals' consent. However, using the biological materials, which were collected by the government as part of their pandemic response for research purposes without consent is a gray area, where the boundaries between pandemic response and research are unclear. With the rapid increase in the amount of data used in medical research, such as big data and artificial intelligence, along with the rising research on human-derived materials, the ethics of medical research in this field is expected to face greater challenges. The 2024 revised Declaration of Helsinki is set to align with the Taipei Declaration, and a revision of the Taipei Declaration is anticipated soon.[30,37]

Table 2 presents a comparative analysis of the research ethics challenges encountered during the COVID-19 pandemic in South Korea and their alignment with the principles and provisions of the revised Declaration of Helsinki. This comparison highlights the congruence between pandemic-specific ethical concerns and the updated global ethical framework, demonstrating how the revised Declaration addresses these challenges. Items marked as “full match” indicate that the issue is explicitly addressed in the Declaration, while those labeled as “good match” represent topics not directly mentioned but reasonably inferred from its principles. Conversely, items marked as “None” denote issues not reflected in the Declaration, with explanations provided for each case.

Among the updates, some revisions of the Declaration of Helsinki explicitly incorporate lessons learned from the global pandemic, reflecting the ethical challenges that arose during this unprecedented crisis. However, as a document designed to provide overarching ethical principles applicable to a broad range of research scenarios, the Declaration does not comprehensively address the unique and specific issues encountered during the pandemics. Consequently, certain principles that emerged as critical during the pandemic were not fully incorporated into the revisions.

While the revised principles of the Declaration of Helsinki provide a solid foundation for ethical guidance in general research contexts, the unique challenges presented by pandemics require additional, specialized ethical frameworks. These complementary frameworks should address the specific ethical dilemmas not covered in the Declaration of Helsinki, ensuring that both general and exceptional circumstances are ethically guided. For instance, one such framework is the PREPARED

Code—A Global Code of Conduct for Research during Pandemics, of which a Korean translation is available.[38]

CONCLUSION

The results of this literature review demonstrate that discussions on research ethics challenges in pandemic Korea align with the principles and recommendations on research ethics established by the international community. Both the Korean government and academia have consistently emphasized the importance of adhering to these internationally established research ethics principles during pandemic-related research and development.

By analyzing the relevance and implications of the challenges identified in this review in relation to the 2024 revisions to the Declaration of Helsinki, this study highlights that most of the ethical challenges encountered in pandemic Korea were indeed reflected in the updated Declaration. The 2024 revision of the Declaration and the Korean literature collectively underscore the critical importance of research ethics in pandemic situations, offering guidance for fostering a more ethical research environment and ecosystem in the 21st century post-pandemic.

In conclusion, while the revised Declaration of Helsinki establishes a robust and comprehensive set of principles applicable to general medical research, addressing the unique ethical challenges posed by pandemics requires additional, specialized ethical codes or guidelines. Emphasizing the preeminence of the Declaration of Helsinki, the PREPARED Code—A Global Code of Conduct for Research during Pandemics is such a framework.[39]

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Table 1. Research ethics challenges during the COVID-19-pandemic-South Korea

Research ethics challenge	Short description	Articles: reference number
1. Prioritization of the safety of research participants	The health and safety of research participants, especially those with severe illness, needs to be protected during a pandemic, i.e. hospital visits should be minimized, drug delivery services be used, and efficacy and safety assessments be conducted online or by phone.	[9-12]
2. Efficient and effective national research governance for crisis response	Well-functioning research governance systems are key to accelerated responses in pandemics, which is why the creation of a central Korean IRB was suggested.	[12-18]
3. Community engagement in research	During a pandemic it is even more important to ensure sensitivity to the local realities, needs, values and culture, and researchers need to engage at all possible stages of the research process.	[13,14]
4. Global solidarity and cooperation for research to respond to the pandemic	In times of international public health crises, the dissemination of accurate information enables countries to take necessary measures and act with global solidarity in the exchange of research results and research products.	[13,14,19]
5. Striving for reliable research and	Unnecessary duplication of research efforts and weak research with insufficient statistical	[13]

	avoiding research waste	power should be avoided, and the activities of research teams could be internationally coordinated to align with global response efforts.	
6.	Rapid and thorough IRB review for crisis response	It is important that ethical review procedures do not delay research processes. Prior to future pandemics, capabilities and structures that provide expertise, efficiency, and expediency, should be put in place.	9,12-14,20
7.	Adaptation of consent for research in pandemic crisis	To reduce the risk of infection transmission, consent processes should be adapted, and for instance, include the possibility for telephone consent.	10-12,14,21
8.	Fair and responsible inclusion of individuals or groups with vulnerability	A fundamental rethink on the inclusion of vulnerable groups in research is necessary to avoid increasing vulnerability when the original intention was to provide protection.	12,22-25
9.	Ethics of human challenge trials	No HCTs were conducted in Korea but it was recommended that future HCTs include securing treatments, producing attenuated strains of pathogens, and implementing safety measures for equivalent pathogens.	13,21,26,27
10.	Use of human materials obtained for pandemic response without consent for research	Whilst securing samples from COVID-19 patients was critical for a prompt public health response, the principle of informed consent must be retained, even during emergencies.	14,29

COVID-19 = coronavirus disease 2019, IRB = Institutional Review Board, HCT = human challenge trial.

Table 2. Research ethics challenges during the COVID 19-pandemic in South Korea mapped against revised Declaration of Helsinki

Research ethics challenge	Declaration of Helsinki addition	Match	Comments
1. Prioritization of the safety of research participants	No significant changes were made on the safety of research participants.	None	The safety of research participants has always been a priority in the Declaration of Helsinki. However, there was no specific mention of heightened attention to the potential risks faced by research participants in the context of a pandemic. This omission may reflect the Declaration's positioning as a set of ethical principles intended to be upheld universally, regardless of specific circumstances such as pandemics.
2. Efficient and effective national research governance for crisis response	The Declaration does not mention national research governance.	None	National responses are not an area that would be covered in a global ethics declaration.
3. Community engagement in research	Revised Article 6 requires "meaningful engagement … during, and following medical research."[3]	Full match	Engagement with all stakeholders in research has emerged over the past decade as a key advancement in research ethics, establishing itself as an essential principle not only during pandemics but in all research contexts.
4. Global solidarity and	No reference is made to	None	Whilst the revised Declaration introduces the concept of 'structural

	cooperation for research to respond to the pandemic	global solidarity.		inequity', no reference is made to global solidarity.
5.	Striving for reliable research and avoiding research waste	Article 21 requires rigorous science to "avoid research waste."[1]	Full match	The importance of avoiding research waste and striving for reliable research became particularly evident during the pandemic. These lessons, drawn also from the pandemic experience, have been incorporated into the revised Declaration of Helsinki, highlighting their necessity as fundamental principles in all research contexts.
6.	Rapid and thorough IRB review for crisis response	Article 23 reinforces the provisions on IRBs, but no reference is made to rapid review.	None	In pandemic situations, the urgency of research and development for swift responses necessitates expedited IRB reviews. However, the Declaration of Helsinki presents advanced ethical principles for IRBs developed over the past decade, applicable not only to pandemics but to all research contexts more broadly.
7.	Adaptation of consent for research in pandemic crisis	Article 26 refines the provisions on informed consent, but no reference is made to adapted consent.	None	Informed consent in pandemics requires adaptation to address increased infection risks and the constraints of isolation or quarantine. However, the Declaration of Helsinki is intended to articulate principles for general contexts and therefore does not specifically address such exceptional

				circumstances.
8.	Fair and responsible inclusion of individuals or groups with vulnerability	Articles 19 and 20 require the fair and responsible inclusion of those in vulnerable situations to avoid exacerbating vulnerabilities.	Full match	Research ethics concerning vulnerable participants has been a critical issue during the pandemic. It has also been a significant area of advancement in global bioethics over the past decade, which is reflected in the revisions to the Declaration.
9.	Ethics of human challenge trials	Human challenge trials are not directly addressed in the Declaration.	None	Article 2 includes healthy volunteers as participants, and Article 7 incorporates advancing public health as a purpose of medical research. This suggests that the Declaration acknowledges the possibility that participants, with free and informed consent, may choose to partake in trials where the benefits primarily accrue to others. Human challenge trials are an example of such trials
10.	Use of human material obtained for pandemic response without consent for research	New article 8 requires that "it remains essential to uphold the ethical principles in this	Good match	The Declaration does not explicitly address the use of human-derived materials collected without consent in pandemic responses. However, it reinforces the principles that research ethics must be upheld even in urgent pandemic situations and that consent is essential for the secondary

	Declaration during … emergencies”[3] and Article 32 provides new guidance on secondary use of data.	use of human-derived materials. While not a complete alignment, it provides a good match with this topic.

IRB = Institutional Review Board.

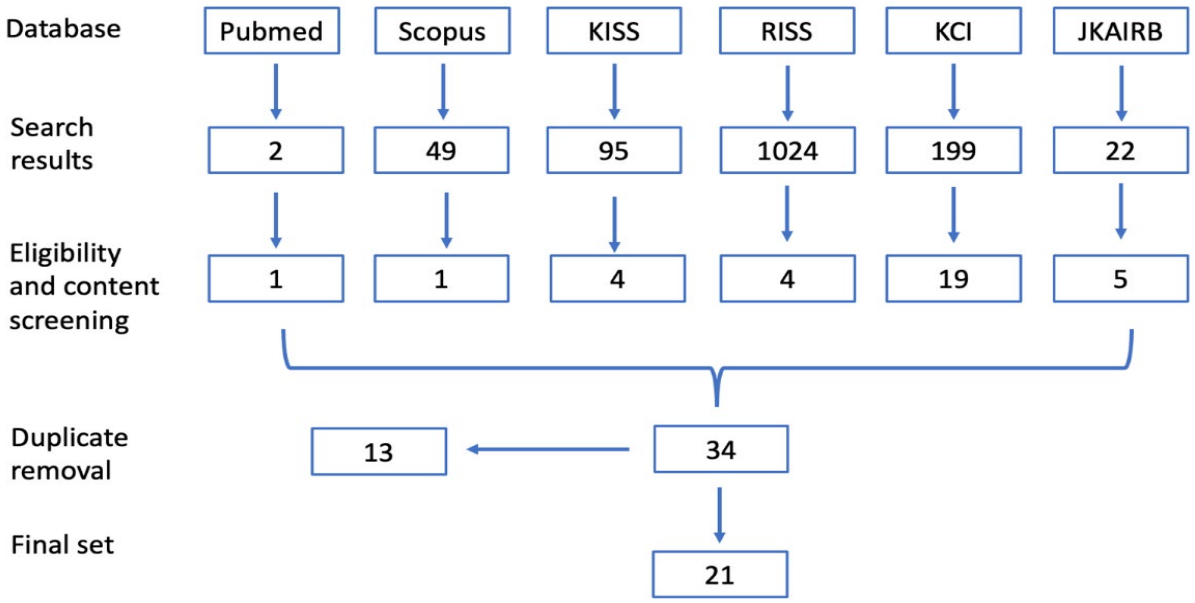

Fig. 1. Flow diagram for academic literature search.

KISS = Korean studies Information Service System, RISS = Research Information Sharing Service, KCI = Korea Citation Index, JKAIRB = Journal of Korean Association of Institutional Review Board database.