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The 2024 Revision of the Declaration of Helsinki and the Future Directions of Korea's Bioethics and Safety Act

Ock-Joo Kim

Department of the History of Medicine and Medical Humanities, College of Medicine, Seoul National University, Seoul, Korea

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Address for Correspondence:
Ock-Joo Kim, MD, PhD
Department of the History of Medicine and Medical Humanities, Seoul National University College of Medicine, 103 Daehak-ro, Jongno-gu, Seoul 03080, Korea.
Email: okim9646@snu.ac.kr

ORCID iD
Ock-Joo Kim
https://orcid.org/0000-0003-4095-4768

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ABSTRACT

In October 2024, the World Medical Association's Declaration of Helsinki (DoH) underwent comprehensive updates that incorporated feedback from global experts and stakeholders. The revised DoH continues to serve as a cornerstone for international and national regulations on medical research ethics. This paper aims to delve into the 2024 amendments to DoH and assesses their impact on South Korea's Bioethics and Safety Act (Bioethics Act). This paper analyses the congruences and gaps between the revised DoH and the current Bioethics Act, examining the alignment and gaps between the current Bioethics Act and the revised DoH. This study identified necessary revisions to enhance the ethical conduct of medical research in Korea in accordance with international standards. A comparison between the principles of the revised DoH and the provisions of the Bioethics Act revealed essential adjustments required to align the Bioethics Act with updated ethical guidelines. These findings underscore the broader implications for Korea's regulatory framework on human research ethics, emphasizing the need for a strategic integration of global ethical standards into the country's legal structure. The revised DoH emphasizes the active role of research participants and the fair inclusion of vulnerable groups. In Korea, the Bioethics Act, last revised in 2013, aligns closely with the DoH but requires further updates to reflect the 2024 amendments.

Keywords: Research Ethics; Declaration of Helsinki; Bioethics; Law; Korea

INTRODUCTION

In October 2024, the World Medical Association (WMA) revised the Declaration of Helsinki (DoH) following a 30-month process that involved contributions from esteemed experts of medical ethics from worldwide.[1] Stakeholders from diverse communities agreed that this revision represents the most thorough and comprehensive update to date, recognizing that the Declaration provides a critical framework for the ethics of medical research in the 21st century and will guide its future development.[2-4] The revision was led by a working group chaired by Jack Resneck Jr. of the American Medical Association.[5] Under his leadership, the group organized eight regional thematic meetings and two public consultations. This global collaboration resulted in a well-rounded and inclusive revision. Additionally, Dr. Park Jung-yul, former vice president of the Korean Medical Association and the first Korean Chair of the WMA, played a key role in organizing the network that facilitated a global consensus among physicians on the revision.[6]

The DoH is a voluntary ethical code for medical research established by the WMA. However, it has long served as the foundation for international regulations by the World Health Organization, the International Council for Harmonisation Good Clinical Practice (ICH-GCP), and national medical research ethics laws in countries in Europe, the United States, Japan, and South Korea.[2,4,5,7] With the recent revision of DoH, countries are now reviewing their national medical research ethics laws to ensure alignment with the 2024 updated version. As the DoH remains central to the legal framework governing medical research ethics in many developed nations, countries are evaluating whether their existing laws need revision to incorporate the 2024 DoH amendments.

In South Korea, the Bioethics and Safety Act (Bioethics Act) was fully revised in 2013 to regulate human subjects research and human material research, incorporating the key principles of the DoH.[8] The DoH, as a living document, has been updated ten times to reflect changes in the research environment and ecosystem, taking into account developments over the past decade. Given that the DoH was revised in 2013, the same year the Bioethics Act was updated, and was revised again in 2024, it is crucial to analyze and address any gaps between the current Bioethics Act and the updated Declaration. This review is essential, as Article 3 of the Bioethics Act emphasizes the need for international cooperation and the adoption of universal international standards to ensure bioethics and safety. Accordingly, the Bioethics Act must be revised to align with the 2024 revision of the DoH. This paper will first outline the 2024 amendments to the DoH, then examine how the current Bioethics Act aligns with these amendments and identify areas where future revisions may be necessary.

OVERVIEW OF KEY AMENDMENTS TO THE DoH IN 2024

The 2024 revisions to the DoH can be grouped into four categories: changes in the concept and perspectives, broadening scope, introduction of new contents, and reinforcement of existing principles, as summarized in **Table 1**. Among these, the first category of changing perspectives involves replacing the term "subjects" with "participants," signifying a shift toward recognizing the rights, agency, and importance of individuals involved in medical research. [5,9] This terminological change reflects a major paradigm shift, transforming the previously passive role of research subjects into that of active participants, empowered to make their own decisions and judgments.[4,10,11] Consequently, the responsibilities of medical researchers have evolved, emphasizing the need for sustained and meaningful engagement with participants throughout all stages of research—before, during, and after the study. Accordingly, the DoH title was revised to Ethical Principles for Medical Research Involving Human Participants. Another related significant conceptual shift is the redefinition of vulnerability as a dynamic and context-dependent concept at the individual, collective, and community levels, moving away from the traditional view of vulnerability as a fixed characteristic of individuals or groups. Additionally, the revised perspective addresses how vulnerable groups have historically been excluded from research participation to prevent exploitation, which inadvertently exacerbates inequalities and reinforces their vulnerability.[5,9-12] To address this issue, the DoH emphasizes the importance of fair and responsible inclusion of people with vulnerability in research. It advocates for special care and protection to ensure these groups are not only safeguarded but also able to share in the benefits of medical research.

The second category of revisions to the DoH involves the expansion of its scope.[5] Previously, the Declaration applied primarily to physicians and was only advisory for others. However,

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Table 1. Categories of key revisions in the 2024 WMA DoH

Contents	Articles
I. Changes in concepts and/or perspectives	
1-1. Change of the term 'subject' to 'participant' out of respect for the rights, agency, and importance of those individuals	§ 1, 2, 5, 6. 7, 9, 10, 12, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37
1-2. Meaningful engagement with potential and enrolled participants and their communities before, during, and following medical research	§ 6
2-1. Changes from vulnerable groups and individuals to vulnerability in individuals, groups, and communities	§ 19, 20
2-2. Excluding these groups from research can worsen disparities, so their fair and responsible inclusion requires special support and protections	§ 19
II. Broadening scope	
2-1. Applicability of DoH beyond physicians into all individuals, teams, and organizations involved in medical research	§ 2
2-2. Adding "respect for" to "protection of" to emphasize the agency of participants	§ 2
2-3. Research participants include both patients and healthy volunteers	§ 2
2-4. The purpose of medical research is to generate knowledge to advance individual and public health	§ 7
2-5. Consistent use of physician and/or other researcher to acknowledge ethical responsibilities apply all those engaged in research regardless of training/profession	§ 9, 10, 12, 18, 26, 27, 28, 29, 30, 31, 32
2-6. Expanding beyond biobanks for the collection, processing, storage, and foreseeable secondary use of biological material and identifiable or re-identifiable data, and to cross-reference the WMA DoT	§ 32
III. New introduction	
3-1. A new aspirational sentence about global justice, which acknowledges structural inequities and urges researchers to carefully consider where and with whom research is carried out	§ 6
3-2. Reaffirmation that public health emergencies do not reduce the importance of DoH principles	§ 8
3-3. A new language on scientific integrity and research misconduct	§ 12
IV. Enhancement of the previous DoH principles	
4-1. A further emphasis on avoiding or minimizing harm to the environment and striving for environmental sustainability	§ 11
4-2. A further emphasis on scientifically sound and rigorous design and execution to produce reliable, valid, and valuable knowledge while avoiding research waste	§ 21
4-3. Enhanced requirements for research ethics committees	§ 23
4-4. Enhanced requirements for free and informed consent	§ 26, 28
4-5. Enhanced requirements for post-trial provisions	§ 34
4-6. Enhanced requirements for unproven interventions in clinical practice	§ 36

WMA = World Medical Association, DoH = Declaration of Helsinki, DoT = Declaration of Taipei.

to enhance the protection and respect for research participants, the 2024 revision explicitly states that the DoH applies to all individuals, research teams, and institutions involved in medical research. Furthermore, to underscore the active role of research participants, the revision emphasizes the importance of respecting participants, going beyond the concept of mere protection. Notably, it clarifies that research participants include both patients and healthy volunteers. Additionally, the revision reaffirms that the primary purpose of medical research is to generate knowledge that advances individual and public health. It further establishes that ethical responsibilities toward research participants are equally applicable to all individuals involved in research, irrespective of their level of training or expertise. Provisions previously confined to biobanks have also been broadened to cover the collection, processing, storage, and secondary use of biological materials and identifiable or re-identifiable data. These provisions are now cross-referenced with the Declaration of Taipei (DoT). Collectively, these updates significantly expand the scope and applicability of the Declaration, redefining its role in contemporary medical research.

The third category of the 2024 DoH involves several new elements introduced. First, a new aspirational statement on global justice has been added, explicitly addressing structural inequities.[3,12,13] It urges researchers to conduct their studies with careful consideration of the structural disparities affecting the populations and locations involved in their research. Additionally, drawing on lessons from the COVID-19 pandemic, the DoH now emphasizes that ethical principles must not be compromised or diminished, even in public health

emergencies where rapid research outcomes are critical.[14] Furthermore, the revised DoH strengthens its focus on research integrity by introducing a new mandatory provision explicitly prohibiting research misconduct.

The fourth consists of the ethical provisions in the previous version both strengthened and enhanced in 2024 DoH.[5,11,15] The 2024 revision places greater emphasis on eliminating, avoiding, or minimizing environmental harm and underscores the importance of striving for environmental sustainability, presenting a much stronger case than earlier editions. Similarly, the provisions regarding scientific design and conduct have been reinforced, highlighting the necessity of generating reliable, valid, and valuable knowledge while avoiding research waste. The statement on the role of research ethics committees has been significantly enhanced, with bolstered requirements for free and informed consent, emphasizing transparent and accessible processes. Additionally, the guidelines for post-trial support have been further developed, while the criteria for employing previously unproven procedures in clinical trials have been made considerably more stringent.

Table 2 compiles the new ethical obligations, referred to as the new ethical imperatives from the 2024 revision of the DoH, where the verb "must" is used to articulate mandatory ethical commitments. These obligations are related to the categories of the 2024 DoH revision as shown in **Table 1**.

ALIGNMENT OF KOREA'S BIOETHICS ACT WITH THE REVISED 2024 DoH

In 2021, South Korea published 83,680 papers indexed in the Science Citation Index (SCI), ranking 12th globally.[16] The total number of citations for Korean papers in 2021 was 169,443,

Table 2. New ethical imperatives with the use of 'must' in the 2024 DoH

Articles	Categories[a]	Contents	Topics[b]
§ 3	[c]	The physician must commit to the primacy of patient health and well-being and must offer care in the patient's best interest.	Physicians' duty
§ 12	III	Involved individuals, teams, and organizations must never engage in research misconduct.	Research integrity
§ 19	I	The harms of exclusion of people with vulnerability must be considered and weighed against any harms of inclusion.	Vulnerability
§ 21	IV	Medical research must have a scientifically sound and rigorous design and execution to produce reliable, valid, and valuable knowledge and avoid research waste.	Scientific requirements
§ 23	IV	The committee must have sufficient resources to fulfill its duties, and its members and staff must collectively have adequate education, training, qualifications, and diversity to effectively evaluate each type of research it reviews.	Research ethics committee
§ 23	IV	The committee must have sufficient familiarity with local circumstances and context, and include at least one member of the general public.	
§ 23	IV	When collaborative research is performed internationally, the research protocol must be approved by research ethics committees in both the sponsoring and host countries.	
§ 32	II	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.	Biological material and data
§ 32	II	A research ethics committee must approve the establishment and monitor ongoing use of such databases and biobanks.	
§ 34	IV	In advance of a clinical trial, post-trial provisions must be arranged by sponsors and researchers to be provided by themselves, healthcare systems, or governments for all participants who still need an intervention identified as beneficial and reasonably safe in the trial.	Post-trial provisions
§ 34	IV	Exceptions to post-trial provisions must be approved by a research ethics committee.	
§ 37	IV	Physicians participating in unproven interventions must first seek expert advice, weigh possible risks, burdens, and benefits, and obtain informed consent.	Unproven interventions
§ 37	IV	Unproven interventions in clinical practice must also record and share data when appropriate and avoid compromising clinical trials.	
§ 37	IV	Unproven interventions must never be undertaken to circumvent the protections for research participants set forth in DoH.	

DoH = Declaration of Helsinki.
[a]Categories shown in **Table 1**, [b]Topics addressed in DoH, [c]DoH cites the revision of the International Code of Medical Ethics.

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also placing South Korea 12th in the world. Clinical medicine accounted for the largest share of Korean publications, with 15,173 papers, representing 18% of the total output. Additionally, South Korea demonstrated significant global standing in clinical trials. In the ranking of clinical trial registrations by country, South Korea placed 4th globally in 2023. Seoul ranked 1st in 2023 city rankings for clinical trial and South Korea was 3rd in single-country clinical trials, maintaining the same rankings as in 2022.[17] Given the substantial international importance and influence of Korea's clinical research and trials, it is crucial for Korean medical and clinical research to remain aligned with global standards. Such harmonization ensures the continued high quality of research while significantly contributing to the respect, rights, and safety of human research participants.

The 2013 amendment of the Bioethics Act of Korea demonstrated the government's efforts to implement the principles emphasized in Article 23 of the 2024 DoH on research ethics committees, with legal mechanisms for evaluating and accrediting the actual implementation of these principles. This indicates that Korea's bioethics operations are quite advanced and aligned with global standards.

The Bioethics Act was enacted in 2004 and enforced in the next year to regulate research involving embryos and genes. This legislation was a direct response to growing ethical concerns surrounding advanced biomedical research. Following the Hwang Woo Suk stem cell research scandal of 2006-2007, which exposed significant ethical lapses and research misconduct, Korea undertook a comprehensive reform of its legal and ethical framework for biomedical research.[18,19] In 2013, the Act was significantly amended to broaden its scope, extending its regulatory authority to encompass all human subjects research and human material research, in addition to its existing regulations on embryos and genes.[8] The amendments require all research institutions conducting studies involving human or human material, embryo research, embryo production institutions, and human material banks to establish institutional bioethics committees (IBCs). These committees are tasked with reviewing, supervising, and deliberating on the ethical dimensions of research conducted within their purview, ensuring compliance with national bioethical standards regardless of the source of research funding.[8]

In addition, the 2013 amendment states that all IBCs must be registered with the Ministry of Health and Welfare (MOHW), and the Minister may support, periodically evaluate, and accredit them.[8] As a result, the MOHW has delegated the National Bioethics Policy Institute as the agency responsible for registering, evaluating, and accrediting IBCs.[20] These IBCs serve as a critical pillar of the infrastructure for biomedical research ethics in Korea. The program to evaluate and accredit IBCs under this Act has evolved from pilot evaluations and the establishment of evaluation criteria (2013–2015) to mandatory evaluations (2016–2019), and to actual evaluation and accreditation since 2021. The MOHW may publish the results of the IBC assessments online. Furthermore, institutions with accredited IBCs can receive additional points for applications for government funding. In hospital evaluations, research management can also be scored higher if the hospital's IBC is accredited by the MOHW. Only IBCs accredited by the MOHW can assume the roles and responsibilities of other IBCs.

The status of IBCs registered with the MOHW under the Bioethics Act is presented in **Table 3** as of September 30, 2024. In total, 967 IBCs are registered with the MOHW in Korea, of which 373 are medical research institutions and 205 are educational institutions.[21] Additionally, 226 institutions rely on IBCs outside of their own institutions, either by utilizing the Public IBC or by entering into agreements with other IBCs. **Table 4** outlines

Table 3. Status of IBC registration with the MOHW of Korea[a] (N = 967)

No. of institutions of direct IBC operation (n = 741, 76.6%)			No. of institutions of relying other IBC (n = 226, 23.4%)	
Medical institutions	Educational institutions	Research institutes	Agreement with the Public IBC	Agreements with other IBCs
373 (50.3)	205 (27.7)	163 (22.0)	131 (58.0)	95 (42.0)

Values are presented as number (%).
IBC = institutional bioethics committee, MOHW = Ministry of Health and Welfare.
[a]As of September 30, 2024, Source: National Bioethics Policy Institute, Status of Institutional Bioethics Committee (IBC) Registrations (Third Quarter of 2024).[21]

Table 4. Status of IBC Accreditation by the MOHW of Korea[a]

Year	Applied IBCs	IBCs that passed document evaluation	IBCs that received on-site evaluation	Accredited IBCs
2021	53	29 (54.7)	29 (54.7)	27 (50.9)
2022	98	61 (62.2)	60 (61.2)	56 (57.1)
2023	96	52 (54.2)	49 (51.0)	44 (45.8)
2024	38	19 (50.0)	17 (44.7)	16 (42.1)
Total	285 (87.0)[b]	161 (56.4)	155 (54.3)	143 (50.1)

Values are presented as number (%).
IBC = institutional bioethics committee, MOHW = Ministry of Health and Welfare.
[a]As of the end of May 2024, Source: National Bioethics Policy Institute, [b]87% of the institutions subject to the evaluation criteria (13% did not submit application due to closure, or non-compliance with the agreement or lack of operating performance).

the status of IBC accreditation by the MOHW as of the end of May 2024. To be eligible for accreditation, IBCs must hold in-person meetings at least four times a year and have reviewed at least 30 initial review cases or above in the last three years. The first cycle of evaluation accreditation took place from 2021 to 2024, with 285 IBCs applying to participate in the evaluation accreditation by the MOHW during the four-year cycle. Only those that pass the initial documentation assessment will undergo a second on-site audit, and the results will be combined to ultimately receive accreditation. Of the total 285 IBCs, 143 were accredited through both the documentary and on-site assessments, representing the accreditation rate of approximately 50%. The accreditation process is conducted every three years, with the possibility of a one-year extension for those demonstrating exceptional performance. Additionally, in cases where accreditation has been obtained through fraudulent means or when the institution no longer meets the required standards, the MOHW has the authority to revoke the accreditation.

In the Bioethics Act, IBCs are evaluated according to a set of 40 evaluation criteria, which are categorized into five areas across two domains: institutional research organizations and the IBC itself.[20] **Table 5** presents these evaluation and accreditation criteria for IBCs under the Bioethics Act. Conceptually, these criteria are aligned with the scope of the United States Human Subjects Protection Program (HRPP). While traditional institutional review boards (IRBs) focus on reviewing and approving research protocols, the IBC assessment and accreditation under the Korean Bioethics Act evaluate two domains – the institution and the IBC.

The first category of the first domain of an institution evaluates whether the institution ensures that the IBC is established in compliance with the law and maintains its independence. The second category evaluates whether the institution possesses the requisite facilities, space, human resources, budget, and training to operate the IBC, as well as its obligation to deliberate on and report any bioethics and safety risks to the relevant government agencies in accordance with legal requirements. Furthermore, it assesses the institution's management of researchers and research staff in compliance with the Act.

The second domain of the IBC examines three categories: composition, operation, and roles and functions. Composition has five standards to evaluate whether the IBC is made lawfully.

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Table 5. IBC evaluation standards by the MOHW of Korea: 40 evaluation standards across 2 domains and 5 categories[a]

Categories	Evaluation standards
I. Institution	
1. Establishment and independence	1.1. The institution establishes the IBC in accordance with Article 10 of the Bioethics Act, considering the characteristics of the research and activities conducted within the institution.
	1.2. The institution ensures the IBC's operational independence by directly establishing it under the institutional official, etc., within the institution.
	1.3. The institution establishes and operates policies and procedures for managing conflicts of interest in the composition and operation of the IBC.
	1.4. The institution establishes and operates policies and procedures to ensure that the institutional official does not approve research protocols that have been disapproved by the IBC.
2. Support	2.1. The institutional official supports the facilities and space necessary for the operation of the IBC.
	2.2. The institutional official provides the human resources necessary to support the operation of the IBC.
	2.3. The institutional official allocates and supports the budget necessary for the operation of the IBC.
	2.4. The institutional official supports education related to bioethics and the IBC for researchers and staff within the institution.
	2.5. The institution establishes and operates reporting criteria and procedures in accordance with Article 11 (4) of the Bioethics Act.
	2.6. The institution has management processes in place to ensure that researchers and staff fulfill their duties as prescribed in the Bioethics Act.
II. IBC	
3. Composition	3.1. The IBC is composed of members in accordance with Article 11 (1) of the Bioethics Act.
	3.2. The IBC has and follows policies and procedures for initial and continuing education for IBC members.
	3.3. The IBC specifies the members required for its operation and defines each member's roles and duties.
	3.4. The IBC chair is elected in accordance with Article 11 (2) of the Bioethics Act and appropriately understands and fulfills the roles.
	3.5. The IBC has and follows policies and procedures for the appointment, reappointment, and resignation of its members.
4. Operation	4.1. The IBC has and follows policies and procedures for preparing IBC meetings, including convening meetings and distributing meeting agendas for review.
	4.2. The IBC has and follows policies and procedures that specify IBC meeting and voting requirements in accordance with Article 8 (2) of the Enforcement Rules of the Bioethics Act.
	4.3. The IBC has and follows policies and procedures to manage conflicts of interest among its members and others involved in the review process.
	4.4. The IBC has and follows policies and procedures for the types and criteria of IBC review decisions, as well as for the follow-up process after these decisions.
	4.5. The IBC has and follows policies and procedures for meeting minutes, including the elements to be included, circulation, and approval processes.
	4.6. The IBC has and follows policies and procedures for review notifications, forms, etc., including review exemptions.
	4.7. The IBC has and follows policies and procedures for the necessary materials and documents required for IBC review (including review exemptions), ensuring their availability to researchers and staff within the institution.
	4.8. The IBC has and follows policies and procedures for record keeping and retention, including archiving (with security management), transfer, or disposal of IBC-related documents, including electronic document.
	4.9. The IBC has and follows policies and procedures regarding requests for information disclosure from research subjects, etc.
	4.10. The IBC supports education for administrative staff to ensure they acquire the necessary expertise for IBC operations.
	4.11. The IBC has and follows policies and procedures for enacting and revising standard operating procedures.
5. Roles and functions	5.1. The IBC has and follows policies and procedures for initial review based on the nature and type of the research.
	5.2. The IBC has and follows policies and procedures for expedited review, if applicable.
	5.3. The IBC has and follows policies and procedures for the exemption of human subjects research and research involving human-derived materials.
	5.4. The IBC has and follows policies and procedures regarding the content of consent forms, the consent process, and waivers of consent.
	5.5. The IBC has and follows policies and procedures for obtaining consent from legally authorized representatives.
	5.6. The IBC has and follows policies and procedures for reviewing safety measures for human research subjects, etc., based on the level of risk involved in the research.
	5.7. The IBC has and follows policies and procedures for reviewing measures to protect personal information, including individually identifiable private information of human research subjects, etc., involved in the research.
	5.8. The IBC has and follows policies and procedures for reviewing the provision of embryonic stem cell lines, personal information, human-derived materials, etc., as well as for the disposal or transfer of human-derived materials, etc.
	5.9. The IBC has and follows policies and procedures for non-research activities required for IBC review in accordance with the Bioethics Act.
	5.10. The IBC has and follows policies and procedures designed to protect the rights and welfare of vulnerable research participants, etc., and ensures compliance.
	5.11. The IBC prepares and provides ethical guidelines for researchers and staff within the institution.
	5.12. The IBC has and follows policies and procedures for continuing review.
	5.13. The IBC has and follows policies and procedures for protocol amendments, violations, deviations, and final study reports, etc.
	5.14. The IBC has and follows policies and procedures for site visits, auditing, and overseeing ongoing research and non-research activities within the institution.

IBC = institutional bioethics committee, MOHW = Ministry of Health and Welfare.

[a]The evaluation standards have been updated based on comprehensive analysis of feedback from the first-phase pilot project (2013–2015) and the second-phase evaluation (2016–2019).

Source: MOWH. Guidelines for Evaluation and Accreditation of Institutional Bioethics Committees.[20]

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Operation includes eleven standards on IBC operation including managing conflicts of interest, convened meetings to review research, and informed consent. The last category, roles and functions, has fourteen standards to evaluate the IBC's roles and responsibilities such as reviewing protocols, oversight of consent process, research audits, etc.

Article 23 of the 2024 DoH is significantly stronger regarding research ethics committees compared to previous versions.[1,5] It asserts that research ethics committees must operate with transparency, possess the independence and authority to resist external pressures, and be sufficiently resourced to fulfill their mandates. Additionally, research ethics committee members and administrative staff must be appropriately educated, trained, qualified, and well-versed in the local context. Over the past decade, the Korean government has invested significant resources into strengthening the capacity of Korea's IBCs through support, evaluation, and accreditation. This ensures that IBCs are well-resourced, supported, and independent. As such, the implementation of these provisions in the 2024 amended DoH has been largely achieved through the first cycle of evaluation and accreditation in Korea.

In addition, the collection, processing, and secondary use of human-derived biological material or identifiable or re-identifiable data, as required by Article 32 of the DoH, have been well established in Korea's Bioethics Act, which has regulated human material since 2013. According to the Bioethics Act, informed consent must be obtained before collecting human material, and future secondary uses must be agreed upon in the consent form. Human material banks are required to be licensed by the relevant national authority to ensure proper governance, including the appointment of an information security manager, provision of adequate facilities and staffing, and adherence to standard operating procedures. Furthermore, the statutory nature of the human material management register and consent form ensures their implementation in Korea's Bioethics Act is more comprehensive than what the DoH mandates.

THE GAP BETWEEN KOREA'S BIOETHICS ACT AND THE REVISED DoH FOR 2024: DIFFERENCES AND FUTURE DIRECTIONS

The 2024 revision of the DoH necessitates further amendments to the Bioethics Act to incorporate these updated principles. A significant shift in perspective is needed, akin to the paradigm shift in the 2024 Declaration, which should also be reflected in Korea's Bioethics Act. The term "human subjects (연구대상자)" in the Bioethics Act positions individuals as passive entities, undermining their autonomy and agency. The term "research subjects," which appears over 40 times in the Act, reinforces this passive framing.[8] This is not merely a linguistic issue but a legal one, as it suggests that individuals are subjected to research rather than actively engaging in research as autonomous participants with agency over their involvement.

While the current law acknowledges the risks of research and emphasizes the protection of subjects, including vulnerable populations, it lacks provisions for their active involvement in research design, implementation, or post-research processes. To align with the principles of the 2024 DoH, it is essential to change the term "research subjects" to "research participants (연구참여자)" throughout the Bioethics Act. Furthermore, the Act must be rewritten to ensure that participants are meaningfully involved in all stages of research. The 2024 DoH advocates

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for the inclusion of research participants and their communities in the design, conduct, and follow-up of research, which should be similarly reflected in the Bioethics Act. Emphasizing that research should be conducted for the benefit of participants, respecting their agency and active involvement, is critical to reframing the legal context to align with these ethical standards.

The most pressing issue in aligning Korea's 2013 Bioethics Act with the 2024 revision of the DoH is its overly restrictive policies regarding research involving vulnerable populations. These policies, which impose excessive protections for groups such as children and individuals lacking decision-making capacity, significantly limit their participation in studies. For instance, the Bioethics Act mandates proxy consent even for minimal-risk research, creating unnecessary barriers to studying vulnerable groups and hindering the collection of data essential for evidence-based interventions. This restrictive approach not only exacerbates health disparities but also contradicts the principles of the 2024 DoH, which advocate for the fair and responsible inclusion of vulnerable populations in research.

The restrictive stance of the Bioethics Act can be traced back to scandals like the Hwang Woo-Suk case, which prompted a cautious regulatory framework to prevent exploitation. However, these measures are now misaligned with the ethical priorities of modern biomedical research, which emphasize participant autonomy and inclusivity. Revising the Bioethics Act to balance participant protection with the removal of unnecessary barriers is crucial for fostering equitable and ethically sound research practices. Such reforms would better align Korea's framework with international standards, enabling greater participation in global biomedical research while ensuring the dignity and rights of vulnerable populations.

The 2024 DoH redefines research participants as collaborative partners in the research process, shifting away from their traditional portrayal as passive subjects. This participant-centered perspective, which recognizes participants as co-creators, addresses the inequities arising from the exclusion of vulnerable groups and underscores the importance of voluntary and active participation. The 2024 DoH emphasizes free informed consent to the research, allowing participants to make informed, voluntary decisions. This voluntary nature hinges on providing accurate, comprehensive, and comprehensible information about the research, including its purpose, risks, benefits, and procedures.[14,22] Participants must be given adequate time and support to make informed decisions, free from coercion or undue influence. Written informed consent serves as a critical safeguard in this process, not merely as a formality but as a reflection of the participant's understanding and agreement to participate.[23] By upholding these standards, researchers can achieve a balanced approach that respects the dignity and rights of participants while ensuring their fair representation in research.

To facilitate the transition toward a participant-centered approach in research, legal changes and modifications to the research environment must be accompanied by comprehensive educational initiatives for participants. Such programs should emphasize their active role in the research process, highlighting their rights, responsibilities, and contributions to advancing scientific knowledge.[24] For instance, tailored informational materials could be developed to explain complex research protocols in accessible language, ensuring participants fully understand the nature of the study and their involvement.[25] Additionally, workshops or interactive sessions could be organized to empower potential participants with knowledge about the ethical frameworks and safeguards that protect their autonomy and well-being. These initiatives would not only enhance participant understanding and trust but

also foster a collaborative research culture where participants are seen as partners rather than mere subjects.[26] Establishing these educational mechanisms could significantly contribute to aligning research practices with global participant-centered standards and improving the overall quality and ethics of research.

The Bioethics Act must be also updated to accommodate future research involving the broad utilization of human-derived materials and data. Since its comprehensive revision in 2013, the Act has remained largely unchanged despite rapid advancements in biomedical research, such as big data, genomics, and artificial intelligence (AI) driven studies. These developments have exposed significant limitations in the current legislation, particularly its reliance on specific consent, which requires narrowly defined research purposes. While specific consent ensures precise data use, its restrictive nature limits research scope, weakens data governance, and undermines data protection.[27]

The Bioethics Act incorporates some elements of broad consent, requiring donor consent, anonymization, and IBC approval for third-party data sharing. However, these provisions, designed prior to the era of big data, fail to address the complexities of global research collaboration and data sharing. The lack of flexibility in adapting to the uncertainties of data-driven research environments results in inefficiencies. While protecting personal information and respecting autonomy remain critical, preparing for unpredictable secondary data use is equally vital.

To address these issues, the Bioethics Act should adopt a framework similar to broad consent as implemented in the United States or in Germany. The framework for broad consent not only aligns with global good practices, such as those implemented in Germany, but also enhances transparency and trust among participants.[28] Broad consent allows participants to provide flexible, comprehensive consent for future data use.[29,30] Frameworks such as the General Data Protection Regulation (GDPR) and the U.S. Common Rule explicitly permit broad consent, enabling data reuse without repeated consent while maintaining strong data protection measures. This approach is particularly effective when specific research objectives cannot be defined in advance. However, broad consent must include safeguards such as pseudonymization to protect privacy and prevent re-identification. The absence of broad consent in the Bioethics Act may present challenges for Korea in aligning with international standards, potentially limiting its role in global research collaboration and data sharing.

Although Korea's Data 3 Laws, comprising the Personal Information Protection Act, the Network Act, and the Credit Information Use and Protection Act, provide a legal foundation for research data use, they have limitations.[31] Excessive pseudonymization can degrade data quality, restricting its usability for research. Moreover, the Bioethics Act lacks clear guidelines for the effective utilization and management of pseudonymized data. The Bioethics Act's insufficient alignment with international standards like GDPR and the Common Rule creates barriers to global research collaboration and data sharing. Revisions to the Bioethics Act should provide data protection measures, safeguard participant rights including the ability to withdraw consent, strengthen oversight by IBC, and offer participants the option to receive information about incidental findings.

The 2024 revision of the DoH does not fully address the challenges posed by evolving research paradigms, such as big data and AI-driven studies.[11] Instead, it links ethical principles concerning human-derived materials to the DoT. Last updated by the WMA in

2016, the DoT provides guidelines for the ethical use of health data and biobanks.[32] However, compared to frameworks like GDPR and the Common Rule, the DoT lacks clear guidance on re-identification risks and adopts a restrictive stance on data sharing, potentially hindering scientific progress. Recognizing these limitations, the WMA has announced plans to update the DoT to reflect current research environments.[5] In the contexts of big data, biobanks, and AI, the revised DoT is expected to emphasize global consistency, participant-centric ethics, and a unified framework for ethical data governance that balances public good with individual privacy.[33]

Korea must closely monitor the updates to the DoT and align its Bioethics Act with these changes. Provisions should incorporate advanced data protection measures, such as pseudonymization, to address re-identification risks, establish transparent frameworks for data sharing that balance participant protection with scientific advancement, and adapt governance mechanisms to the dynamic nature of data-driven research. By aligning its Bioethics Act with updated principles from the DoH, the DoT, and international standards, Korea can strengthen its regulatory framework, enhance global research collaboration, and ensure ethical and effective use of human materials and health data. Such reforms will address the dual imperatives of protecting personal information and advancing research capabilities, positioning Korea as a key player in ethical and innovative biomedical research.

To advance international medical research ethics in line with the updated DoH domestically, it is crucial to maintain and enhance national capabilities in medical research ethics. Key aspects include continuous education and training of relevant researchers, the development of related professionals, and the establishment of a national-scale network to support these efforts. In Korea, the legal foundation for strengthening IBC capabilities has been established through evaluation and certification under the Bioethics Act. However, only about 50% of institutions currently hold accreditation, indicating the need for continuous enhancement and standardization. The professionalization of IBC personnel is necessary to align with globally advancing research ethics standards and ecosystems.

The Korean Association of Institutional Review Boards (KAIRB), founded in 2002, has grown into a national network dedicated to education, training, and policy discussion on research ethics.[34] Initial surveys revealed that domestic IRBs lacked quality and standardization.[35] However, since the implementation of the Bioethics Act and its comprehensive revision in 2013, both the quantity and quality of domestic IRBs have improved significantly. Moving forward, IRB administrators should be recognized as a specialized professional group with relevant expertise, gaining social recognition. IRB members must continuously develop their review skills to keep pace with advancements in science and ethics. Researchers should be educated on research ethics and IRBs during their training and apply the principles of the DoH and the Bioethics Act in their research activities.

Public Responsibility in Medicine and Research (PRIM&R), founded in 1974,[36] promotes ethical research standards through education and certification, including the Certified IRB Professional (CIP) program established in 1999.[37] Together, they have significantly enhanced research ethics and human subject protection in the USA and worldwide. Similarly, it is time for KAIRB, now 22 years old, to establish a program for educating and certifying domestic IRB professionals to enhance national capacity in research ethics.

CONCLUSION

The 2024 revision of the DoH introduces significant updates to address the ethical complexities of contemporary biomedical research, emphasizing transparency, participant-centered approaches, and strengthened safeguards. These revisions highlight the need for Korea to review and update its Bioethics Act to reflect evolving international standards. Aligning domestic regulations with the updated DoH principles will enhance ethical governance, improve protections for research participants, and ensure the integrity and quality of biomedical research in Korea. Such efforts will also promote international collaboration and trust in the global research community.

To implement these updates effectively, it is crucial to enhance the capabilities of IBCs, provide specialized training for their members, and encourage meaningful engagement with research participants. The KAIRB can play a central role by advancing education, fostering policy discussions, and potentially establishing a certification program to standardize and professionalize IBC practices.

By updating its regulatory framework and strengthening institutional and professional capacities, Korea can contribute meaningfully to the global advancement of ethical biomedical research while ensuring robust protections for research participants.

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