*Clin Eval*. 2025; 52(3). W28-39.



# Patient Public Declaration of Research Ethics (1st edition) :

## Research ethics of the people, by the people, for the people —Expanding the impact of the 2024 revision of the Declaration of Helsinki[1]

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**Abstract**

We have been continuing to learn about the World Medical Association (WMA)'s Declaration of Helsinki (DoH), having monthly online meetings since 2020. During the series of meetings, we published a paper in Japanese titled "Our WMA Declaration of Helsinki" to communicate the contents of the DoH in our own language to people in the same position as us. It consists of three parts:

(1) A reproduction of each paragraph of the DoH;

(2) A paraphrase of each paragraph of the DoH in our own plain language;

(3) Our opinions on each paragraph of the DoH.

Prior to this publication, we published a paper in English extracting and reconstructing our opinions in the above third part.

Now we come to proclaim the "Patient Public Declaration of Research Ethics", in both Japanese and English, based on our opinions submitted to the WMA for the 2024 revision of the DoH. This Declaration is developed with our hope that the ethical principles presented here, although not included in the 2024 revision of the DoH, will become universal common research ethics norms in the future, on the premise that the DoH will be adhered to.

In order to create new ethical norms responding to the emerging social issues, with a vision of what we should aim for in the future, we proclaim this Patient Public Declaration of Research Ethics.

**Kew words**

Patient public involvement, research ethics, the Declaration of Helsinki, fundamental human rights, patient right

[1] This article is re-constructed from previously published articles (references 3, 4) with some new contents and in the style of a declaration as a whole. The English version was first published on 10 October 2024, prior to the 2024 revision of the Declaration of Helsinki, in the website of *Clinical Evaluation*. Vol. 52, No. 3, followed by Japanese version on January 9, 2025. These Preprint versions were replaced with the final versions, at the time of printed journal publication in February 25, 2025, which includes only Japanese version.

## Background of the Patient and Public Declaration of Research Ethics

We are members of Bioethics Working Group of the Japanese Institute for Public Engagement (Ji4pe). We are learning the systems of healthcare and drug development from the perspective of patients and the public. Among various agendas, we are exploring since 2020 the World Medical Association (WMA)'s Declaration of Helsinki (DoH)[1], the ethical principles for medical research involving human participants, through monthly online meetings[2]. Patients and healthy people first encounter the DoH in an informed consent documents when they are requested to participate in medical research. Many of them would give consent to participate in research without knowing the contents of the DoH.

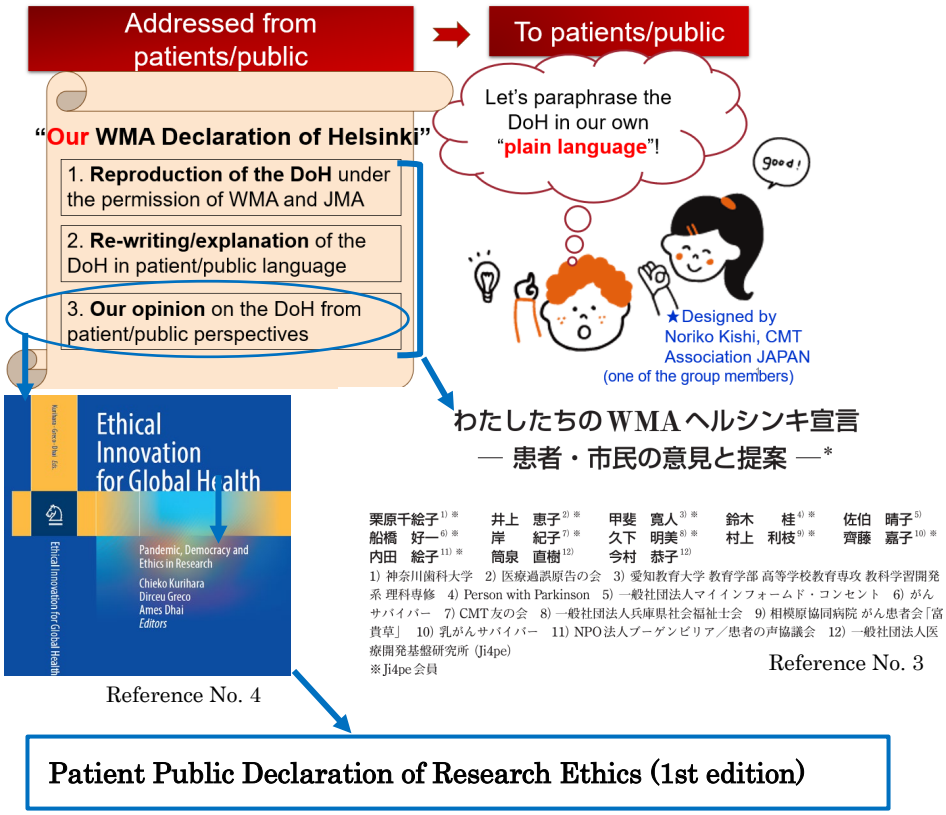
Because the texts of the DoH is difficult for the general public to understand, a group member proposed that we should produce a document called "Our WMA Declaration of Helsinki"[3], which will be communicated in our own language to people in the same position as us. It consists of the following three descriptions for each paragraph of the DoH（Fig.1）.

**(1) A reproduction of each paragraph of the DoH, using the Japanese translation by the Japan Medical Association (JMA) (based on the permission of the WMA and JMA)**

**(2) A paraphrase of each paragraph of the DoH in our own plain language**

**(3) Our opinions on each paragraph of the DoH**

Fig. 1 "Our WMA Declaration of Helsinki (DoH)"



In the course of this activity, an extraction of part (3) was re-constructed in English and included as a chapter of a book published by an international publisher[4]. During a webinar to disseminate the publication of this book, Professor Ames Dhai, one of the editors of the book, acknowledged that the opinions had important significance which is not found in the DoH, and encouraged us to issue a declaration of research ethics by Japanese patients and the public, After the publication of this chapter of in English text, we published a paper in Japanese "Our WMA Declaration of Helsinki", consisting of the three parts mentioned.

The DoH was first published in 1964. The 2024 revision to the 2013 version is the tenth and latest. In February and July of 2024, we submitted our opinions to the draft revision of the DoH, responding to the two instances of public consultations organised by the WMA.

While some of our opinions are reflected in the revision, not all are. For this reason, we have decided to publish the Patient and Public Declaration on Research Ethics, in order to disseminate the 2024 revision of the DoH and expand its impact. Our Declaration is based on the premise that the DoH will be adhered to, and constructed with the hope that the newly presented ethical principles not included in the DoH will become the universal research ethics norms in the future.

This first edition is based on an agreement among the authors. We wish to update it in collaboration with domestic and international patients and public.

## Development of cutting-edge technologies and patient public involvement

The development of cutting-edge technologies is now being pursued in various forms, bridged from basic research to human applications, and then commercialisation. Development of technologies that can artificially create human life and mental activity is progressing, including artificial intelligence that uses accumulated personal data, manipulation of genetic information such as genome editing, technology to create and fertilize eggs and sperm from iPS cells, and brain organoids. In order to adequately consider the impact of these technologies on the human mind, society, future generations, and on ecosystems, it is necessary to involve patients and the public from the early stages of research and development.

Protecting health and well-being, living with and overcoming illness or disease are not an issue for individuals or families alone, but for society as a whole. It is necessary to consider social issues that emerge as technology continues to advance, overviewing a diverse and changing society from ethical and inclusive perspectives. With this Patient and Public Declaration of Research Ethics, we aim to create new ethical norms responding to these emerging social issues.

# Patient Public Declaration of Research Ethics[2]

## 1. Purpose and scope

The Patient and Public Declaration on Research Ethics is a declaration of ethical principles for research involving humans, of the patient and public, by the patient and public, for the patient and public. Our Declaration requires all those who conduct health research involving humans to adhere to the World Medical Association (WMA)'s Declaration of Helsinki (DoH) (Box 1).

Our Declaration covers health research involving not only living humans, but also research on prenatal embryos, foetuses, deceased persons, and materials or data derived from humans.

On the premise that the DoH is adhered to, we declare additional ethical principles, most of which are not included in the DoH, which was developed primarily by physicians. Our Declaration aspires for its principles to be recognized in the future as world common norms, addressing all patients and the public, which include physicians and other experts.

**Box 1 Principles of research ethics established until the 2013 revision of the Declaration of Helsinki (Summary. Key words are in bold.)**

■**Preamble**
- The Declaration of Helsinki is an **ethical principle for medical research involving humans**.
- The Declaration covers research on not only **living persons** but also **individually identifiable human materials and data**.

■**General principles**
- **The rights and interests of research participants take precedence over the goal of research to generate new knowledge**.
- Research must be conducted only by **qualified** individuals.
- **Harms resulting from participation in research** must be appropriately **compensated** and necessary **treatment** must be provided.

■**Risks and benefit**
- **Risks benefits assessment**, **risk minimization** and **risk management** are continuously required. Research may not be initiated or continued unless the **benefits outweigh the risks**, and must be discontinued if necessary.

■**Research protocol and Research Ethics Committee approval**
- Research may not be initiated or continued unless a **research protocol** describing the design and performance of the research has been approved by a **research ethics committee**.

■**Informed consent**
- Participation of individuals giving **informed consent** must be **voluntary**, after

[2] A summary of the principles established by the 2013 version of the DoH is given in Box 1, and in the text of this Declaration, statements based on the new principles in the 2024 revision of the DoH are given with article numbers in the form of (§1) , and statements based on the principles already in the 2013 version of the DoH are given in the form of (§1, 2013), with the article number of 2024 version.

adequate necessary information is provided. For a potential participant incapable of giving consent, informed consent from an authorised representative is required. In this case, assent from this individual must be sought.

■Placebo use and post-trial provisions

- The benefits, risks of a new intervention must be tested against those of the best proven intervention, if there is. Exceptional comparison with placebo or no intervention may be acceptable if there is no additional risk of serious or irreversible harm resulting from not receiving the existing best proven intervention.
- Provisions for post-trial access for participants who still need the tested interventions should be made in advance of starting clinical trial.

*Acceptable risk in this case described in the CIOMS guideline is "no more than a minor increase above minimal risk".

**There are opinions that post-trial access should be ensured to trial participants, not only making provision in advance, and to host community as well as those in need globally.

■Research registration and publication

- Research must be registered in a publicly accessible database before recruitment of the first participant. Results must be accurate and must be published even if the results are not what is expected.

■Unproven Interventions in Clinical Practice

- An unproven intervention may be used by a physician for a treatment of a patient, under some limited conditions, including seeking for expert advice, obtaining informed consent from a patient or representative. This intervention should subsequently be made the object of research to evaluate its safety and efficacy.

Source: Summarized from the World Medical Association's Declaration of Helsinki: Ethical principles for medical research involving human subjects, 2013 version.

## 2. Fundamental principles

### 2.1 Research ethics principles in plain language

Research ethics principles must be described in plain language that can be understood by all.

### 2.2 Ethical principles based on universal human rights norms

This Declaration is based on internationally recognised norms of fundamental human rights[5678], patient rights[9], and principles of medical ethics[1011].

Both researchers and research participants should be aware of these basic norms.

### 2.3 Research ethics principle based on responsibility and awareness as "research participants"

The rights of research participants （§ 1 and others） must be respected and assured.

On this premise, research participants will take on the role of a collaborative partner to co-create research, with appropriate responsibilities and awareness.

Furthermore, we wish to establish research ethics principles covering ethics of patient-initiated research.

### 2.4 Promotion of patient and public involvement

We will participate proactively in research and development of medical products, and healthcare policy.

Additionally, we will advocate and support the participation of those who are unable to proactively express their wishes, and will deliberate together with them how their meaningful participation （§6） should take place.

### 2.5 Respect for human rights and welfare of research participants

The core principle of the DoH stating that the rights and interests of research participants takes precedence over the goal of research （§7, 2013） must be upheld at all times.

### 2.6 Realising the value of research

The ultimate goal of medical research is to realise holistic healthcare through recognising the fundamental rights of patients, considering diversity, and respecting the values of the communities of the research participants.

Everyone involved in research should share this goal as a core “value” of research.

### 2.7 Prevention of discrimination and stigmatization, and consideration of the impact on the environment, society and future generations

Discrimination and stigmatisation of individuals due to the conduct or results of research must be prevented.

All those who are engaged in research must consider the impact of the research on human society, the human mind, future generations, and the sustainability of ecosystem.

For this reason, patient and public involvement from the early stage of research and development program （§6） is required.

### 2.8 Advocate the rights and interests of the vulnerable and promote their participation in research

The participation of vulnerable people in research provides opportunities for their social inclusion. Their contribution to the improvement of the well-being of their community and beyond creates valuable research for society as a whole.

People who have particular difficulties in expressing and making decisions due to their physical or social conditions are more likely to be put at risk of research. They are also likely to be disadvantaged in the sharing of benefits from research. Because of these reasons, they must receive additional protection （§6, 19, 20, 2013）.

Any form of exploitation in the name of research must be prohibited.

Self-advocacy of vulnerable people to express their views and make their own decisions,

as well as advocacy on their behalf must be promoted.

### 2.9 Ensuring the scientific validity of research and animal welfare

Scientific validity and research integrity must be assured（§21, 22, 2013）, avoiding research waste（§21）, and strictly prohibiting research misconduct（§12）.

Conduct of animal experimentation must be in accordance with the principles of 3Rs (Replacement, Reduction, Refinement). Animal welfare （§21, 2013）must be respected.

## 3. Research Ethics Committees

### 3.1. Diversity of Research Ethics Committees and patient public involvement

Diversity of Research Ethics Committee members must be assured and participation of members representing patients and the public must be promoted（§23）.

Members representing the patients and the public must respect the perspectives of those who are unable to express their opinions, ask appropriate questions, express opinions, and will participate in deliberations and voting, taking given responsibilities.

### 3.2 Open recruitment for fairness

Research Ethics Committees must ensure transparency, independence （§23, 2013）and fairness in their establishment, membership and operation.

The selection of committee members must not be arbitrary. There must be a system whereby motivated members who have achieved relevant systematic education program are assigned through open recruitment. They are given training opportunities, and eventually replaced after serving a certain period of time, so that they can be followed by well-trained successors.

### 3.3 Assessment of advanced technology, impact on society and future generations

It is desirable that Research Ethics Committees have the function to deepen the discussions on the impact of advanced medical technologies on society and future generations that emerge from the review of individual research protocols, and to present views as ancillary opinions, and encourage a conversation within society.

## 4. Informed consent

### 4.1 Informed consent and shared decision-making

A person's decision to participate in research must be based on fully informed understanding and the free and voluntary consent（§25, 2013）.

Explanations about the research must be given in a way that is understandable（§26）

to candidate participant and that correctly conveys the nature of the research.

Research participants must be guaranteed the right to disagree, discontinue participation or withdraw consent without detriment（§26）.

In addition to the assurance of individual informed consent, patient-centered, shared decision-making should be promoted, collaborating with the patient's family members, supporters, physicians and a multidisciplinary research team. They can work together on a treatment plan, including whether or not to participate in research, and continuously review the patient's participation in research as circumstances change.

### 4.2 Advocating decision-making for people without capacity to consent.

For a person who is incapable of giving informed consent, due to immaturity or physical or mental situations, the representative must advocate for the patient's will, including previously expressed ones（§28）, and the best interest of the candidate participant.

In addition, advocacy and support are required so that such a person can express an assent（§29, 2013）, an expression of willingness to participate in research, after receiving sufficient information adjusted to the person's comprehension level.

### 4.3 Dignity and rights of persons without capacity to consent and without relatives

The representation of decision-making of persons who do not have the capacity to consent, have no relative and are unable to give their own or proxy consent even at a later date has not been adequately considered[12].

We wish to discuss from the perspective of patients and the public the rights and conditions for participation in research of such persons, who would be the most vulnerable.

### 4.4 Broad informed consent and dynamic consent

The Declaration of Taipei for Health Databases and Biobanks[13] must be adhered to where data or materials obtained in research may be subject to secondary use（§32）.

When a research participant gives consent to the secondary use of materials or data, the consent should be "broad informed consent" based on sufficient understanding of the information given as far as possible about the purpose, who could use, and the governance arrangement of possible future secondary uses. We request that instructions on how to access the secondary use information be disclosed and the right of withdrawal of consent be assured.

We wish to promote an emerging concept of "dynamic consent", which means giving continuing consent to the use of material or data, being informed about a new secondary use, the progress of the research, as well as any other relevant information generated from research, including how to access the secondary use information and the right to refusal or withdrawal[14]. We hope for the development of social consensus for the methods and

procedures for such type of consent and an environment where participants can make adequate decision.

### 4.5 Right to know and right not to know

A research participant's "right to know" and "right not to know" must be respected. Any meaningful information for an individual participant, including secondary findings obtained from research, must be explained according to their wishes, based on due consideration of its scientific validity and its clinical significance in the treatment program.

## 5. Principles of controlled clinical trials and post-trial access

### 5.1 Controlled clinical trials

Clinical trials comparing treatments（§33, 2013） are conducted when it is not known which method is better.

We will be able to make a decision whether or not to participate in a placebo-controlled trial only when the significance and the compelling reasons are explained.

When there is a safe, effective treatment, it is essential to compare with it. Nevertheless, if placebo-controlled trial is conducted in such setting, placebo-related risk must be minimal.

We wish to be involved in the discussion on acceptable condition of the placebo use, from the perspectives of patients and the public.

### 5.2 Post-trial access

Research participants (patients) still in need for safe and effective treatment proven in the research（§34, 2013） should be provided with the treatment after the completion of the trial.

Research is co-creation involving patients and the public and the results of research are to be delivered to future society. To ensure that the results from research could be accessed from those who need them, we will work together with those involved in research to develop the infrastructure to realise post-trial access.

## 6. Publication of research results

### 6.1 Database registration of research

All information of research and its findings must be free and accessible to all, and registered in a publicly accessible database（§35, 2013）.

The results of the research should be released with a lay summary written in plain language understandable for the general public.

### 6.2 Journal publication of research

For the purpose of promoting patient public involvement, “open access” of the report in peer-reviewed journal should be facilitated so that everyone can read the full text through fair and equitable cost-sharing.

“Open science” should be also promoted so that the data supporting the research results can be disclosed to the public or shared conditionally with those who need them. In addition, “citizen science” where patients and the public can make use of such data and participate in the research process should be promoted.

## 7. Unproven treatments

The DoH states that physicians may use some unproven treatment for patient care under some conditions but recommends that it should be made objective of research to evaluate its safety and efficacy（§ 37, 2013）.

When unproven intervention is used, relevant data should be accumulated and safety and efficacy should be monitored.

## 8. The wishes of patients and the public

Medical care and research depend on a trust between physicians/researchers and patients and the public.

The goal of medicine is not to pursue profit, but to move towards holistic care and realise the physical, mental and social well-being of humans.

Research is altruistic in nature and is supported by the altruism of all involved. Study results are “gifts” to future patients and the public.

We believe that protecting the rights of patients means protecting the rights of physicians.

We must always be aware that healthcare is based on research supported by such ethical foundation.

In order to create new ethical norms responding to emerging social issues, with a vision for the future, we proclaim this Patient and Public Declaration of Research Ethics.

## Conflict of interest

There is no conflict of interest to be declared related to this article.

KS is an employee of ASKA Pharmaceuticals.

## Acknowledgment

We appreciate Ms. Midori Senoo, Managing Director, Myotonic Dystrophy Patients' Group

of Japan (DM-family), and Ms. Konomi Wakasa (Patient's Association of Nesidioblastosis) who participated in some part of our series of web meetings and provided meaningful opinions. We also appreciate Prof. Dirceu Greco (Professor Emeritus of Infectious Diseases and Bioethics at the School of Medicine, Federal University of Minas Gerais, Brazil) and Prof. Ames Dhai (Professor Bioethics, School of Clinical Medicine, University of the Witwatersrand, South Africa), editors of the book which includes our chapter where our original ideas related to this declaration was expressed. Lastly, we appreciate Ms. Nami Saito, who provided language review on the final English version of this manuscript.

## Author contribution

This article is a re-construction from the previous publications noted at the top page. All contents are constructed from the opinions expressed from authors including patients and the public: HK, who has made the most critical reconstruction and YS, HK, YF, KI, NK, AK, TM, KS, and EU. Among them, KS is an expert in drug development. AK practices as a qualified mental health social worker. CK edited the words expressed by them into terminology used in research ethics. KI consulted as an expert of medicine and drug development. Contributions of all the authors are accordance with the recommendation of the International Committee of Medical Journal Editors.

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