

Co-organized by:

The Brazilian Society of Bioethics (SBB); International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP); Clinical Evaluation Inc.; The 129th Pharmaceutical Study Group

*Patient and Public Opinions  
to the Revision  
of the Declaration of Helsinki:  
Our Proposals to the WMA*

**presentation by Yoshiko Saito, breast cancer survivor**

Fellow Member of the Japan Association for Bioethics

Slides prepared in collaboration with Prof. Chieko Kurihara,

based on discussions among patients and the public

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**1 Background**

**2 Our Opinion on the WMA's Draft Document  
for Revising the \*Declaration of Helsinki**

**3 Future perspectives**

**\*DoH**



# Contents

## 1 Background

## 2 Our Opinion on the WMA's Draft Document for Revising the Declaration of Helsinki

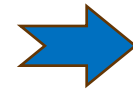
## 3 Future perspectives

# Declaration of Helsinki

## 2020 Establishment of Ji4pe\* Working Group

\*Japanese Institute for Public Engagement

Addressed from physicians



To physicians

Patients and the general public will read the informed consent section in the form asking to participate in medical research.



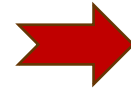
The text is **difficult** to understand, e.g., double-negative phrases...



★Designed by  
Noriko Kishi,  
CMT Association JAPAN  
(one of the group members)

# OUR WMA Declaration of Helsinki

Addressed from  
patients/public



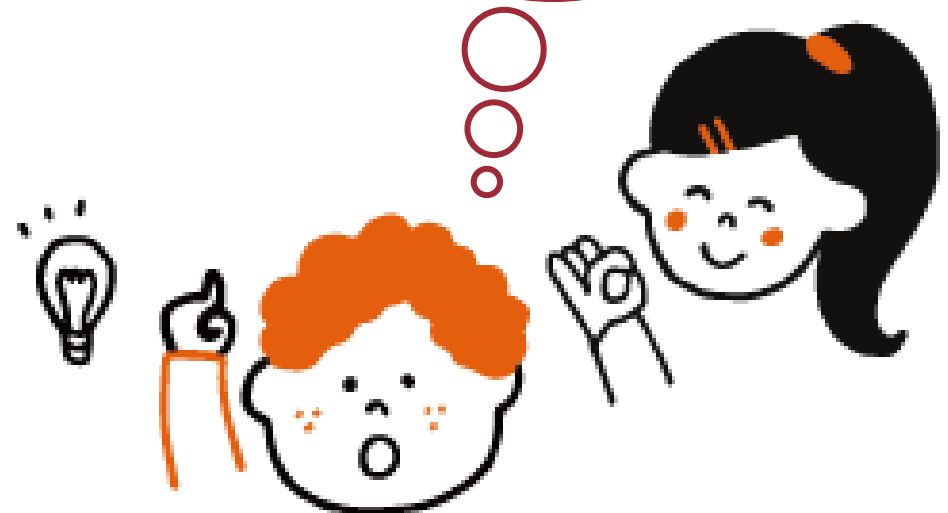
To patients/public

## Our WMA Declaration of Helsinki

1. **Reproduction of the DoH** under the permission of WMA and JMA
2. **Re-writing/explanation** of the DoH in patient/public language
3. **Our opinion** on the DoH from patient/public perspectives

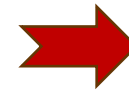
Let's re-write the DoH  
in our own  
**“plain language”!**

Good!



# OUR WMA Declaration of Helsinki

Addressed from  
patients/public



To patients/public



## Our WMA Declaration of Helsinki

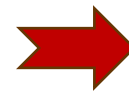
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## Our “WMA Declaration of Helsinki”: Opinions and Proposals from Patient and Public for Research Ethics

Chieko Kurihara, Keiko Inoue, Hiroto Kai, Katsura Suzuki, Haruko Saeki, Yoshikazu Funabashi, Noriko Kishi, Akemi Kuge, Toshie Murakami, Yoshiko Saito, Eiko Uchida, Naoki Tsutsumi, and Kyoko Imamura

# OUR WMA Declaration of Helsinki

Addressed from  
patients/public



To patients/public

## Our WMA Declaration of Helsinki

1. Reproduction of the DoH under the permission of WMA and JMA

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ISSN 0300-3051  
臨床評価  
Clinical Evaluation Vol. 52, No. 1, Jul. 2024

次世代の研究開発基盤・コロナ禍を超えて  
改正次世代医療基盤法による  
Real-World Data (RWD) の利活用促進について  
高齢者の終末期ケアにおける遠隔医療の役割  
10年以上の製薬企業勤務経験を有する  
医師・研究者を対象にしたキャリア調査結果と考察  
国立感染症研究所が提示する超過死亡数を  
解釈する場合の注意点

【国立感染症研究所が提示する超過死亡数を  
解釈する場合の注意点】についての編集部注記  
超過死亡: “事実を事実として知る”とはどういうことか?  
日本におけるCOVID-19パンデミック時の  
mRNA 監視ナノ粒子ワクチン3回接種後の  
がん年齢調整死亡率上昇

「ヘルシンキ宣言」2024年改訂に向けて  
- 「グローバルヘルズのための倫理的イノベーション」 -  
わたしたちのWMAヘルシンキ宣言  
患者・市民の意見と提案

プラセボ対照試験の倫理:  
COVID-19パンデミックの経験を含む歴史的な分析  
試験終了後アクセス・COVID-19パンデミックの  
経験を考慮した歴史的な分析

臨床評価刊行会

提案  
わたしたちのWMAヘルシンキ宣言  
- 患者・市民の意見と提案 -\*

栗原千絵子<sup>1)</sup> 井上 恵子<sup>2)</sup> 甲斐 寛人<sup>3)</sup> 鈴木 桂<sup>4)</sup> 佐伯 晴子<sup>5)</sup>  
船橋 好一<sup>6)</sup> 岸 紀子<sup>7)</sup> 久下 明美<sup>8)</sup> 村上 利枝<sup>9)</sup> 齊藤 嘉子<sup>10)</sup>  
内田 絵子<sup>11)</sup> 簡泉 直樹<sup>12)</sup> 今村 恭子<sup>12)</sup>

1) 神奈川県立大学 2) 医療過誤報告の会 3) 愛知教育大学 教育学部 高等学校教育専攻 数科学習開発  
系 理科専修 4) Person with Parkinson 5) 一般社団法人マインフォームド・コンセント 6) がん  
サバイバー 7) CMT友の会 8) 一般社団法人兵庫県社会福祉士会 9) 相模原協同病院 がん患者会「富  
貴草」 10) 乳がんサバイバー 11) NPO法人ブーゲンビリア / 患者の声協議会 12) 一般社団法人医  
療開発基盤研究所 (J4pe)  
\* J4pe 会員

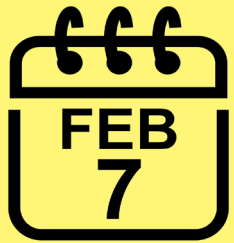
Our “WMA Declaration of Helsinki”  
- Opinions and proposals from patient and public -

Chieko Kurihara<sup>1)</sup> Keiko Inoue<sup>2)</sup> Hiroto Kai<sup>3)</sup> Katsura Suzuki<sup>4)</sup> Haruko Saeki<sup>5)</sup>  
Yoshikazu Funabashi<sup>6)</sup> Noriko Kishi<sup>7)</sup> Akemi Kuge<sup>8)</sup> Toshie Murakami<sup>9)</sup>  
Yoshiko Saito<sup>10)</sup> Eiko Uchida<sup>11)</sup> Naoki Tsutsumi<sup>12)</sup> Kyoko Imamura<sup>12)</sup>

1) Kanagawa Dental University 2) Association for Medical Malpractice Victims 3) Aichi  
University of Education (Science Course, Major in High School Education, Faculty of Education,  
Faculty of Education 4) Person with Parkinson 5) My Informed Consent 6) Cancer  
Patient and Survivor 7) CMT Association JAPAN 8) Hyogo Association of Certified Social  
Workers 9) Sagami-hara Kyodo Hospital Cancer Patients' Association "Hakukiso" 10) Breast  
cancer survivor 11) Breast Cancer Patient Support Group BOUGAINVILLEA / Patients-voice  
council 12) Japanese Institute for Public Engagement (J4pe)  
\* Member of J4pe

\* 本報は下記の既発表英文論文の記述内容の日本語版を大部分に含むが、当初より下記論文と本報の出版を計画して取  
組んできた活動の成果である。下記論文と本報の関係は、下記論文及び本報中に説明されており、下記論文の出版  
社も了承している。  
Kurihara C, Inoue K, Kai H, Suzuki K, Saeki H, Funabashi Y, Kishi N, Kuge A, Murakami T, Saito Y, Uchida E,  
Tsutsumi N, Imamura K. Our “WMA Declaration of Helsinki”: opinions and proposals from patient and public for  
research ethics. In: Kurihara C, Green D, Ekai A, editors. Ethical innovation for global health: pandemic, democracy and  
ethics in research. Springer; 2023. p. 243-69. 以下、書籍のサイト:  
<https://link.springer.com/book/10.1007/978-981-99-6163-4>

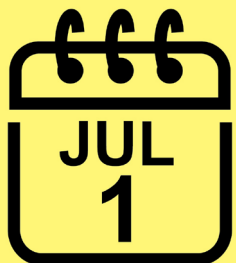
# Explanation / Opinions on the DoH by Patients & Public addressed to Patients & Public



**Submitting our opinions  
in response to WMA's call for  
public consultation  
for the revision of the DoH**



**Establishment of  
NEW Bioethics Working Group  
of the Ji4pe**



**Publication of  
“Our WMA Declaration of  
Helsinki” in Japanese**



# International Norms

The necessity of a shared understanding among members

Let's deepen our understanding of the foundations of research ethics principles.1/2

WHO Constitution 1946

vs

Japanese Constitution §25



Health as a Human Right



UN Universal Declaration  
of Human Rights  
1948

vs

Japanese Constitution §13  
and other sections

# International Norms

## The necessity of a shared understanding among members

Let's deepen our understanding of the foundations of research ethics principles. 2/2

cf. South African Constitution: Right of research participant



UN International Covenants  
of Human Rights 1966

vs



Clinical Trials 2017

Equal rights of all the research participants. Not Limited to Medical Research

International standards  
of Personal Data Protection Laws  
(OECD, EU-GDPR)

vs

Japanese Act  
of Personal Information Protection

Privacy protection in research ethics principles

# Other important principles by the WMA

How about the care?

**Medical Ethics**  
(Modernized  
Hippocratic Oath)

**Declaration of Geneva**  
1948, last amended 2017

**Research Ethics**

**Declaration of Helsinki**  
1964, last amended 2013  
To be amended 2024

**Professional Code of Physicians**

**International Code of  
Medical Ethics**  
1949, last amended 2022

**Patient Rights in Research and in Medical Care**

**Patient Rights  
Declaration of Lisbon**  
1981, last revised 2015

**Declaration of Patient Safety**  
2002, revised 2012

**Health Databases and Biobanks**

**Declaration of Taipei**  
2002, revised 2016

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## **2 Our Opinions on the WMA's Draft Document for Revising the Declaration of Helsinki**

- 1) Three Key Points  
in the WMA Draft Document**
- 2) Main Opinions We Submitted to the WMA  
During the Two Public Consultation**

## **2 Our Opinions on the WMA's Draft Document for Revising the Declaration of Helsinki**

**1) Three Key Points  
in the WMA Draft Document**

**2) Main Opinions We Submitted to the WMA  
During the Two Public Consultation**

# Three Key Points in the WMA Draft Document

**1**  
Simplifying  
the language



**2**  
Participants  
Not Subjects

**3**  
Ensuring  
Participants protection



## **2 Our Opinions on the WMA's Draft Document for Revising the Declaration of Helsinki**

**1) Three Key Points  
in the WMA Draft Document**

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During the Two Public Consultation**





# Public Consultations



**Prof. Chieko Kurihara**  
supporting our group discussion



**Acknowledgment**



**Comment preparers**

# Main Points of Our Public Comments Submitted to the WMA 1/2

**#1** Social Value towards achieving the SDGs

**#2** Finding advocates to protect the rights and interests of participants who can't consent.

**#3** Promoting Shared Decision Making

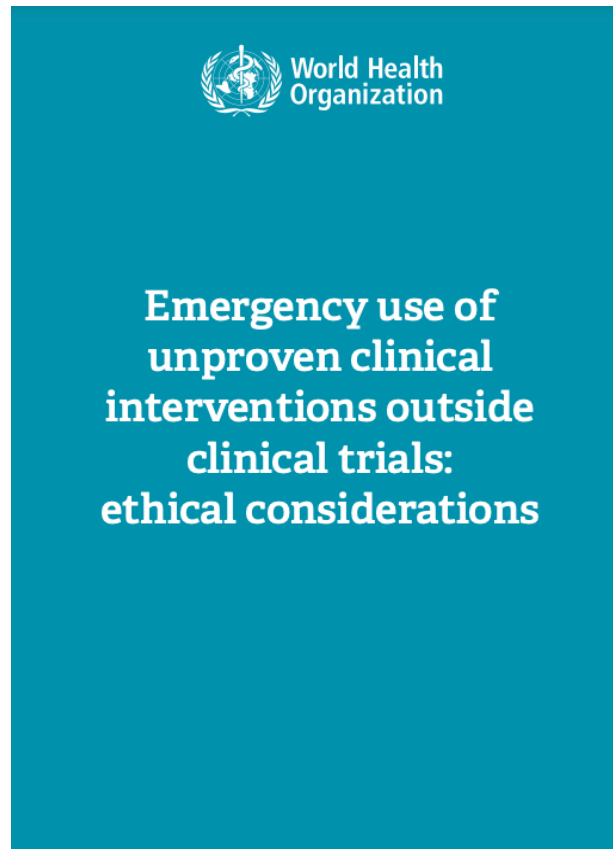
**#4** the fairness of research ethics committees

**#5** Patients struggle to understand placebo use when an intervention is already proven.

**#6** We believe that post-trial access should be guaranteed and included in the informed consent form.

# Main Points of Our Public Comments Submitted to the WMA 2/2

## #7 Comparison with WHO



**Broad Informed Consent  
& Dynamic Consent**

**the Right to Know  
& the Right Now to Know**

**Open Access & Open Science**

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# Future perspectives



**Bioethics working group  
comprised of patient and public  
as one of the working groups of Ji4Pe**



- 1 Develop a patients and public research ethics statement**
- 2 Publish the 2<sup>nd</sup> edition of OUR WMA Declaration of Helsinki**
- 3 Conduct a survey on Patients and public participation regarding a medical care based on the report from CIOMS**

# Patient and public perspectives on the WMA Declaration of Helsinki

## WMAヘルシンキ宣言への患者・市民の意見

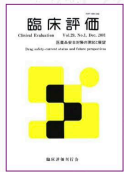
### Rinsho Hyoka (Clinical Evaluation)

Japanese/English

Last Updated: 20 Jul. 2024

**Current Issue**

Rinsho Hyoka (Clinical Evaluation) Vol. 52, No. 1, Jul. 2024  
 Cornerstone of next generation research and development: Overcoming COVID-19 pandemic /  
 For the 2024 revision of the Declaration of Helsinki: From the "Ethical innovation for global health"



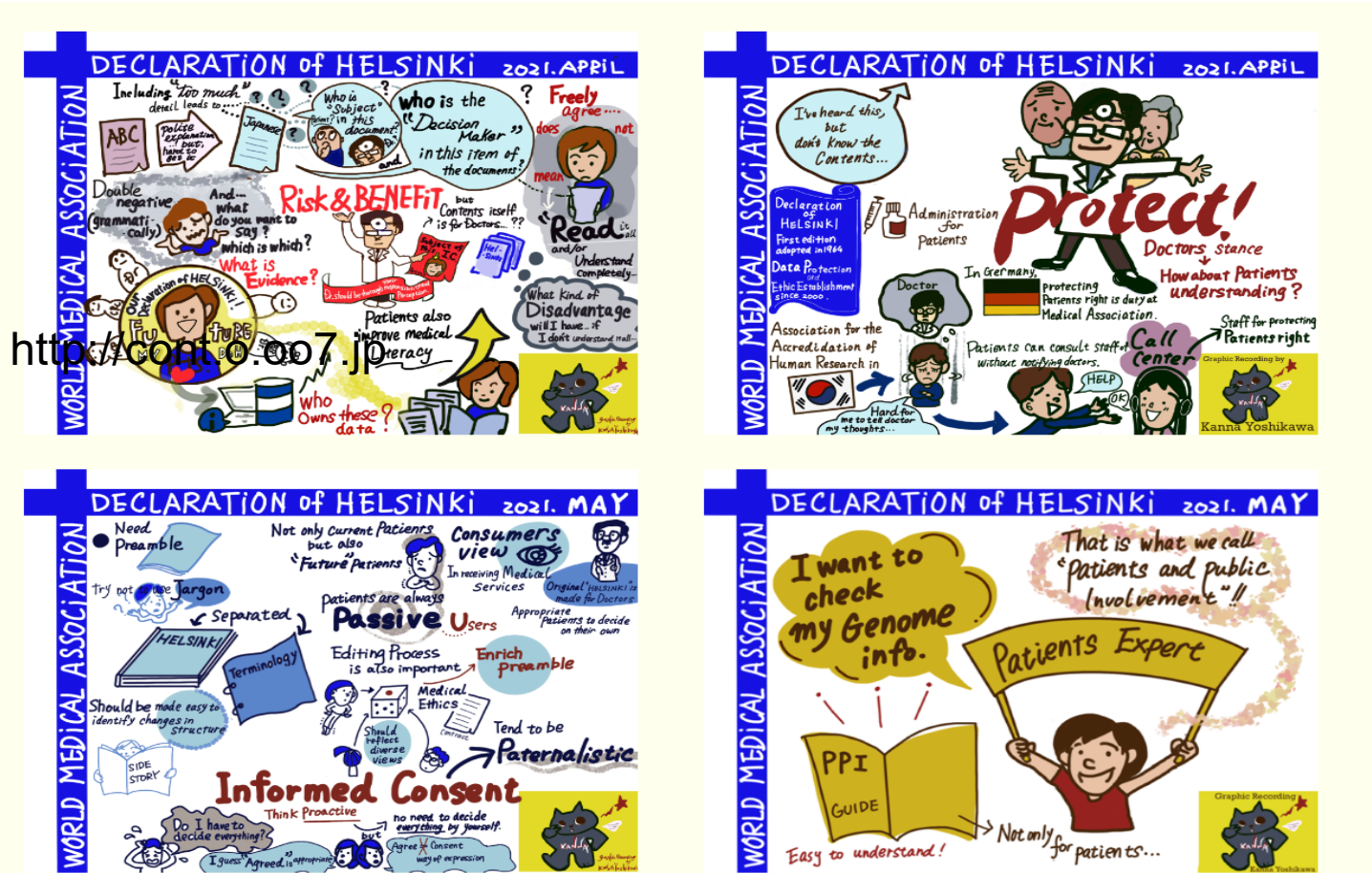
Rinsho Hyoka  
(Clinical Evaluation)



Controller Committee

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Graphic Recordings by Kanna Yoshikawa



*Thank you for your attention!*

**Acknowledgment: Members of the Bioethics Working Group of Ji4pe**



**Yoshiko Saito**



**Yoshikazu Funabashi**



**Keiko Inoue**  
previous leader



**Hiroto Kai**



**Noriko Kishi**



**Akemi Kuge**



**Prof. Chieko Kurihara**  
our mentor



**Toshie Murakami**



**Katsura Suzuki**



**Eiko Uchida**

**Special  
Thanks to  
President  
of Ji4pe**



**Dr. Kyoko Imamura**  
President, Ji4pe