

Pandemic, Democracy and  
Ethics in ResearchChieko Kurihara  
Dirceu Greco  
Ames Dhali  
Editors

## Part II Historical and International Perspectives on the Development of Ethical Principles in Research Involving Humans.

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

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

## Presentation

### Keiko Inoue

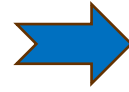
Association for Medical Malpractice Victims

### Eiko Uchida

President, Breast Cancer Patient Support Group BOUGAINVILLEA  
Patients - Voice Council

# Positioning of the Declaration of Helsinki (DoH)

Addressed from physicians



To physicians

Patients and the general public will see the title for the first time in an informed consent document when they are requested to participate in the medical research.

**Difficult** to understand, e.g., double-negative phrases...



★ Designed by Noriko Kishi (one of the authors)

# Three reports on our discussions, including Graphic Recording

A group of Patient Public Involvement (PPI) shared their feelings after reading "DECLARATION OF HELSINKI":

- **Part 1** The atmosphere of the meeting is vividly reported with Graphic Recording. *Clin Eval.* 2021; 49(1).
- **Part 2** The launch of developing "MY/OUR DECLARATION OF HELSINKI". *Clin Eval.* 2021; 49(2).
- **Part 3** Graphic Recording of the discussion on placebo-controlled trial and post-trial access. *Clin Eval.* 2021; 49(Sup 38).



一般社団法人医療開発基盤研究所 臨床評価研究会 共催 日本生命倫理学会 JI4PE 日本製薬医学会 JPhMed 医療  
臨床研究リスク管理研究会 協力

生命倫理セミナー

# バイオエシックスの 展開とSDGs

参加  
無料

バイオエシックスのグローバルな展開のルーツと  
未来へのSDGs (持続可能な開発目標)

BIOETHICS SEMINAR

2022年1月22日(土)

日時 13:30 ~ 15:30

場所 オンライン (zoom)

対象 生命倫理にご興味のある方

定員 300名 (先着順)

患者の権利って?  
インフォームド  
コンセントってどう  
いうこと?

講師紹介

早稲田大学名誉教授

木村 利人 氏

法学修士  
博士 (人間科学)

早稲田大学大学院法学研究科修了後、タイ、ヴェトナム、スイス、アメリカなどでバイオエシックスを研究。早稲田大学人間科学部において教授に就任。「幸せなら手をたたこう」の作詞者でもある。

身近にある医療の「倫理」とはなにか?  
患者はどんな権利を持っているのか?  
生命倫理にとってのSDGsとは?  
いのちを守り育てる市民の活動を長年続け  
てきた倫理の専門家のお話を伺います。

お申込み

コチラのQRコードもしくはURLのgoogle form  
よりお申し込みください。  
<https://forms.gle/LaUvcHLrHurTyEzv&>

お問合せ 一般社団法人 医療開発基盤研究所 JI4PE 検索  
e-Mail : info@ji4pe.tokyo

※本講演会は録音・録画し、録音録画コンテンツが公開されます。予めご了承ください。

## Bioethics Seminar No. 1

Rihito Kimura.

The roots of global development of bioethics and SDGs to bridge the rights of patients and public to the future generation. 2022 January 22.

Clin Eval. 2022; 50(3): 299-324.

一般社団法人医療開発基盤研究所 臨床評価研究会 共催 日本生命倫理学会 JI4PE 日本製薬医学会 JPhMed 医療  
臨床研究リスク管理研究会 協力

生命倫理セミナー 第2回

# 患者が考える 生命倫理

参加  
無料

医療の受け手である患者が自身の体験に基づいて  
倫理の在り方を考える

BIOETHICS SEMINAR

最近にある医療の「倫理」とはなにか?  
患者はどんな権利を持っているのか?  
近頃の医療先進 (生命倫理研究会) に行き参  
見。今回は当事者として医療に巻き合っ  
てきたお二人にお話を伺います。

講師紹介

内田 絵子 氏

医学博士 (臨床検査学)

臨床検査技師 内田 絵子  
臨床検査技師 村上 利枝

2022年2月23日(水)

日時 13:30 ~ 15:30

場所 オンライン (zoom)

対象 生命倫理にご興味のある方

定員 300名 (先着順)

お申込み

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<https://forms.gle/Wro0vSdJ4suMNBA>

お問合せ 一般社団法人 医療開発基盤研究所 JI4PE 検索  
e-Mail : info@ji4pe.tokyo

※本講演会は録音・録画し、録音録画コンテンツが公開されることを特約しております。

## Bioethics Seminar No. 2

Eiko Uchida, Toshie Murakami.

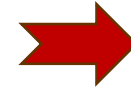
Patient-oriented bioethics: considering about ethics based on the patient's experience of themselves of users of medical care. 2022 Feb 23.

Clin Eval. 2022; 50(3): 325-60.

★Poster designed by Hiroto Kai (one of the authors)

# Positioning of the “**Our** WMA Declaration of Helsinki (DoH)

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 in patient/public perspectives

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

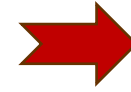
Good!



★ Designed by  
Noriko Kishi  
(one of the authors)

# Positioning of the “**Our** WMA Declaration of Helsinki (DoH)

Addressed from  
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To patients/public

## Our WMA Declaration of Helsinki

1. **Reproduction of the DoH** under the permission of WMA and JMA
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2023



**A summary of authors' opinions on the points NOT included in the DoH and should be discussed for future revision**

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- **Early evaluation of the research and development plan considering the impact on study target populations, society, global situations, and future generations.**
- **Strengthening patient/public perspectives in the ethical principle beyond the scope of self-autonomous norms by and addressed to physicians.**

## A summary of authors' opinions on the points NOT included in the DoH and should be discussed for future revision

- **Early evaluation of the research and development plan considering the impact on study target populations, society, global situations, and future generations.**
- To **avoid discrimination or stigmatization** against the study's target populations.
- Aiming at UN's Sustainable Development Goals (**SDGs**).
- Evaluating the impact on **future generations**, the **environment**, and **society**.



- **Strengthening patient/public perspectives in the ethical principle beyond the scope of self-autonomous code by and addressed to physicians.**

- Using **plain language**, e.g., avoiding “**double-negative**” phrases.
- The scope of the Declaration needs respecting **embryos, fetuses, and the dead** when being studied.
- Promotion of **patient and public involvement in** each process of research
- **Multidisciplinary collaboration**, including patient peer supporters.
- **Shared decision making** based on informed consent.
- **Diversity and fairness of Research Ethics Committee** membership.
- Protecting dignity and rights of an individual **incapable of consent and no available relative**
- To develop international research ethics principles agreed among **all the relevant stakeholders, NOT ONLY PHYSICIANS.**

# One of the limitations

- One of the limitations for us is about the **placebo-controlled study** where there is a proven intervention.
- We had discussion many times but for patient/public, **it was difficult to understand why placebo study is necessary when there is a proven intervention.**
- The description about the risk in the DoH was difficult for us to understand.
- This means that it would be **difficult for most of the candidate research participants to understand.**



United Nations  
<https://www.un.org/sustainabledevelopment/news/communications-material/>



Breast Cancer Patient Support Group  
 BOUGAINVILLEA's activity for Medical Aid  
 Overseas: collecting used post stamps and plastic  
 bottle caps.

- Set the goal of research to lead the United Nation's **SDGs**.  
 Beyond individual interests of researcher of financial gain of companies.
- Medicine is **Treasure** of our society, **global public good**.
- Health is **fundamental right** of human being, equally shared among all.
- Study results are "**gifts**" to future patients and public.

<http://cont.o.oo7.jp/grareco.html>

## 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

[Back Numbers of Clinical Evaluation](#)

[「臨床評価」誌 バックナンバー一覧へ](#)

**Webinar on November 6,  
with the presentations of  
almost all the authors.**

We discussed the World Medical Association's Declaration of Helsinki from the perspective of patients and public, and published papers in Japanese together with "Graphic Recording", in the journal "*Clinical Evaluation*" (see below).

Succeeding English paper to consolidate our opinions is included in a book entitled "*Ethical Innovation for Global Health: Pandemic, Democracy and Research in Ethics*" (Springer Nature, Nov. 2023). The English versions of the Graphic Recordings were created for this book. The original Japanese versions can be accessed from the papers below.

Webinar in Japanese on our paper: Nov. 6, 2023.

[Webinar in English by the authors of the Springer book: Dec. 4, 6, 2023.](#)

わたしたちは、患者・市民の視点で世界医師会「ヘルシンキ宣言」について議論し、グラフィックレコーディング作品とともに下記の日本語論文を『臨床評価』誌に発表しました。

これらの意見をまとめた英語論文は『グローバルヘルスのための倫理的なイノベーション：パンデミック、民主主義、研究倫理』という書籍にて発表予定です（Springer Nature社、2023年11月）。英語版のグラフィックレコーディング作品は同書籍のために作成され、このページで公開しています。オリジナルの日本語版は下記の日本語論文からアクセスできます。

[2023年11月6日\(月\)にウェビナーを開催しました。](#)

[発表資料](#)

[動画](#)

[Slide with English](#)

- **Whole the presentations, Video in Japanese**
- **My presentation with English translation**

*Thank you for your attention!*

**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**

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Prof. Rihito Kimura, Bioethics teaching  
Ms. Mariko Mimura, Attorney-at-law  
Ms. Kanna Yoshikawa, Graphic recordings  
Prof. Dirceu Greco & Ames Dhari, editors  
Patient public participants at the meetings.