

The 2024 Declaration of Helsinki: Taking Forward Bioethics and Human Rights

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

Supported by The Japan Association for Bioethics (JAB)

Cooperation: Japanese Association of Pharmaceutical Medicine (JAPhMed); Japanese Institute for Public Engagement (Ji4pe); Clinical Research Risk Management Study Group

共催 : ブラジル生命倫理学会、国際製薬医学会 (IFAPP) 、
臨床評価刊行会、第 129 回くすり勉強会

後援 : 日本生命倫理学会

協力 : 日本製薬医学会 (JAPhMed) 、医療開発基盤研究所 (Ji4pe) 、
臨床研究リスク管理研究会

Monday, 5, 26, August 2024 Zoom webinar

Brazil 8:00-11:00; US Washington DC 7:00-10:00;

Japan 20:00-23:00; CET/South Africa 13:00-16:00

Registration required, free of charge : 登録必須・無料

<https://forms.gle/hWcumg8WiVGJUoQU6>

Background and objectives

The World Medical Association (WMA)'s Declaration of Helsinki (DoH), ethical principles for research involving humans, was first adopted in 1964 and last amended in 2013. It is currently in the final stage of the next revision, with the adoption proposed to be in October 2024. Critical topics which have been discussed thus far in the WMA's regional meetings and twice during public consultations are: involvement and protection of patients and community in research; promoting inclusion and protection of vulnerable people; research in low-resource settings including disaster situations; access to interventions proven to be effective; and the most controversial issue of the condition of placebo-controlled trials when proven intervention exists (including consistency with CIOMS guidelines). Linking of the issues with the WMA Declaration of Taipei on Health Databases and Biobanks is also an important topic to promote data-driven research.

This symposium will provide an overview of the revision process of the WMA, from an external perspective (including the view with some collaborative relationship with the WMA), and consider the direction ahead from the perspective of the cornerstone for the protection of the dignity and rights of research participants in the context of bioethics.

背景と目的

世界医師会による人を対象とする研究の倫理原則であるヘルシンキ宣言は、1964年に初版が採択され、最新改訂は2013年である。現在、2024年10月の改訂版採択に向けた最終段階にある。世界医師会の地域会議と2回のパブリックコンサルテーションでは、コミュニティや患者の研究への参画とその保護、弱者の研究組み入れ推進とその保護、低資

源環境・災害状況下での研究、試験終了後に有効性が証明された介入へのアクセス、そして最も論争を喚起してきたプラセボ対照試験の許容条件（CIOMS 指針との整合性）などが重要な争点となっている。ヘルスデータベースとバイオバンクについての台北宣言との関係性もデータ駆動型研究を推進する上で重要課題である。

本シンポジウムでは、第三者的な立場（協力関係を持つ場合を含む）から、世界医師会における改訂状況を概観し、今後の研究倫理の潮流の方向性を検討するとともに、研究参加者の尊厳と人権の保護のために必要な基軸を、生命倫理学の観点から明らかにする。

* All of presentations are panelists' personal view, not of affiliations, not explanation from WMA's side, unless there is specific reference.

Panelists (titles in blue are tentative)

- 1) Dirceu Greco, M.D., Ph.D., Professor Emeritus of Infectious Diseases and Bioethics at the School of Medicine, Federal University of Minas Gerais, Brazil; Past President of the Brazilian Society of Bioethics, Member of the UNESCO International Bioethics Committee; Associate Member of the World Medical Association
[Ethics of placebo-controlled trials and post-trial access: Brazilian experience](#)
- 2) Elda Coelho Azevedo Bussinguer, J.D. PhD (Bioethics). Full Professor at the Faculty of Law of Vitória (FDV), Brazil; President of the Brazilian Society of Bioethics
[Welcome from Brazilian Society of Bioethics on the Declaration of Helsinki](#)
- 3) Diego Zanella, PhD (Philosophy), Professor of Bioethics, Universidade Franciscana, Brazil, Member of the Board Brazilian Society of Bioethics
[Perspectives from Brazilian Society of Bioethics on the Declaration of Helsinki](#)
- 4) Laís Alves de Souza Bonilha, PhD (Local Health Development). Associate Professor at the Federal University of Mato Grosso do Sul, Brazil; Coordinator of the CONEP (Brazilian National Commission on Ethics in Research)
[Experience of CONEP to facilitate Ethical Research](#)
- 5) Varvara Baroutsou, M.D., Ph.D., President of the International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine (IFAPP), Consultant in Internal Medicine and in Pharmaceutical Medicine, Athens, Greece
[Collaboration with the WMA and IFAPP's perspective](#)
- 6) Kotone Matsuyama, PhD. Professor, Department of Health Policy and Management, Nippon Medical School, Member of the Japan Association for Bioethics; Chair of Ethics Working Group of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)
[Commitment of the Ethics Working Group of the IFAPP](#)
- 7) Chieko Kurihara, BA, Specially-appointed Professor, Kanagawa Dental University; Vice-chair of Certified Review Board, National Institute for Quantum Science and Technology; Member of the Japan Association for Bioethics; Member of Ethics Working Group of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)
[Overview of the revision process of the 2024 Declaration of Helsinki \(1\)](#)
- 8) Takeo Saio, M.D., Department of Internal Medicine and Psychiatry, Fuji Toranomon Orthopedic Hospital; Member of the Japan Association for Bioethics; Associate Member of the World Medical Association
[Overview of the revision process of the 2024 Declaration of Helsinki \(2\)](#)

- 9) Yoshiko Saito, Master of School Design, Breast cancer survivor; Fellow Member of the Japan Association for Bioethics
[Patient and public opinions to the revision of the Declaration of Helsinki: our proposals to the WMA](#)
- 10) Ames Dhai, MBChB., LL.M., Ph.D., Professor Bioethics, School of Clinical Medicine, University of the Witwatersrand, Specialist Ethicist at South African Medical Research Council, Johannesburg, South Africa; Past Chairperson of the UNESCO International Bioethics Committee; South African Medical Association
[Access and Equity in Research: Justice, Vulnerability and Low-Resource Settings](#)

背景となる出版

Background publications

- 日本生命倫理学会 COVID-19 タスクフォース・ブラジル生命倫理学会 共催企画
Co-organized by the COVID-19 Task Force, Japan Association for Bioethics & Brazilian Society of Bioethics
 - ・ COVID-19 と生命倫理 Part 3 : パンデミックと研究倫理－民主主義, プラセボ, 試験終了後アクセス
<http://cont.o.oo7.jp/49sup38/49sup38contents.html>
 - ・ (英語版)
COVID-19 and bioethics Part 3: Pandemic and research ethics－Democracy, placebo and post-trial access
http://cont.o.oo7.jp/49sup38/49sup38contents_e.html
 - ・ COVID-19 と生命倫理 Part 1 ブラジル生命倫理学会勧告 No. 01/2020 と直面する課題
http://cont.o.oo7.jp/48_3/ab-p551.pdf
 - ・ (英語版)
COVID-19 and bioethics: Part1 Ethical Challenges and COVID-19: The Recommendation No. 01/2020 of the Brazilian Society of Bioethics (SBB)
http://cont.o.oo7.jp/48_3/p661-84.pdf

今回のオーガナイザーによる関連テーマの出版

- Recent collaborative publications by co-organizers
 - ・ Kurihara C, Greco D, Dhai A, editors. Ethical innovation for global health: pandemic, democracy and ethics in research. Springer; 2023.
<https://link.springer.com/book/10.1007/978-981-99-6163-4>
 - ・ Kurihara C, Baroutsou V, Becker S, Brun J, Franke-Bray B, Carlesi R, Chan A, Colli LF, Kleist P, Laranjeira LF, Matsuyama K, Naseem S, Schenk J, Silva H and Kerpel-Fronius S. Linking the Declarations of Helsinki and of Taipei: Critical Challenges of Future-Oriented Research Ethics. Front. Pharmacol. 2020. 11: 579714.
doi: 10.3389/fphar.2020.579714
<https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2020.579714/full>
 - ・ Kurihara C, Kerpel-Fronius S, Becker S, Chan A, Nagaty Y, Naseem S, Schenk J, Matsuyama K, Baroutsou V. Declaration of Helsinki: ethical norm in pursuit of common global goals. Front Med (Lausanne). 2024 Apr 2; 11: 1360653.
doi: 10.3389/fmed.2024.1360653. PMID: 38628806; PMCID: PMC11019506
<https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2024.1360653/full>