Kotone Matsuyama,
Board of Officers, Chair of Ethics WG, IFAPP

COMMITMENT OF THE ETHICS WORKING GROUP OF THE IFAPP

Greeting from IFAPP President

“I sincerely apologise that circumstances have prevented me from being here today to extend a warm personal welcome.

However, I extend my warmest greetings and my deepest gratitude for your presence, which will enrich our perspectives and discourse.

I would like to express my gratitude to the organising committee and especially to my colleagues in the IFAPP Ethics Working Group, Prof. Chieko Kurihara and Prof. Kotone Matsuyama, our distinguished speakers and each and every participant.

This webinar is not just an academic or theoretical exercise; it is a call to action.

As we delve into the issues of the ongoing revision of the Declaration of Helsinki, your views and questions may have transformative potential for human life and bioethics.

Your input and our discussions can influence actionable change in medical research for the benefit of research participants.

Without further ado, I wish you a stimulating dialogue and mutual inspiration.”

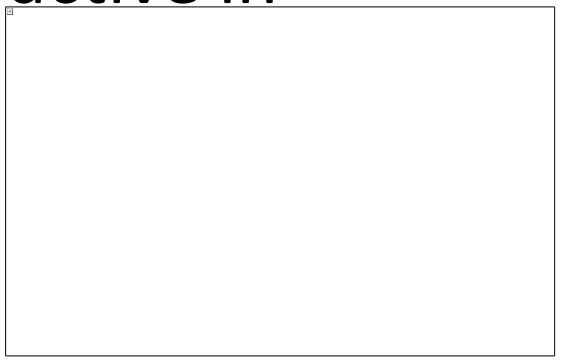
Varvara Baroutsou
IFAPP President

About IFAPP

(International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine)

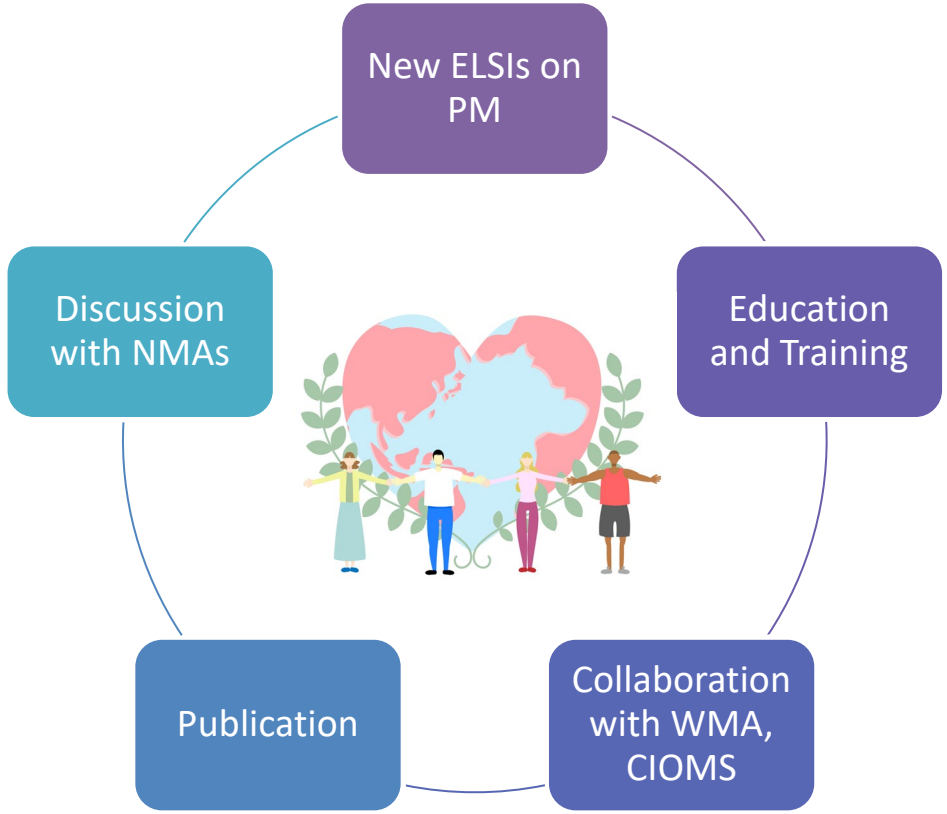
- Since 1975, IFAPP's primary objective is to bring together physicians and scientists from the pharmaceutical industry and contract research organisations with colleagues working in research institutes, academia, medicines regulatory agencies and patient organisations, in order to stimulate the advancement of knowledge in Pharmaceutical Medicine globally.
- Currently, 25 National Member Associations (NMAs) represent the interests and goals of several thousand professionals active in Pharmaceutical Medicine

https://ifapp.org



IFAPP Ethics WG

- The aim of this Ethics Working Group (EWG) is to share and deepen the understanding of the wide range of ethical issues in Pharmaceutical Medicine, and to share current topics and their potential solutions. Currently, the EWG is working on the following topics on an ongoing basis:
  - Recommendations for the revision of the World Medical Association's 'Declaration of Helsinki'.
  - Ethical issues in clinical trials in disaster settings.
  - Ensuring access to new investigational drugs and vaccines and benefit sharing.
  - Ethical principles and frameworks in Pharmaceutical Medicine.
- The EWG will monitor new trends in research ethics and raise awareness publicly.
- **<u>Joint Activities;</u>**
  - CIOMS WG on Principles of Good Governance for Research Institutions (PGGRI)
  - Considerations for the Declaration of Helsinki; preparation for publication – The World Medical Association



MEMORANDUM OF UNDERSTANDING
BETWEEN
THE WORLD MEDICAL ASSOCIATION (WMA)
AND
THE INTERNATIONAL FEDERATION OF
ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS (IFAPP)

Signed in two original copies in English.
Chicago, 14 October 2017

For the
World Medical Association

Otmar Kloiber
Secretary General

Yoshitake Yokokura
President

For the
International Federation of
Associations of Pharmaceutical Physicians

Gustavo Kesselring
International Affairs

Honorio Silva
President

MoU

"WMA and IFAPP agree to co-operate and consult each other…"

➔Mutual collaboration with WMA

WMA Regional Meetings

(video-recordings available at URLs)

- December 9 – 11, 2022 Tel Aviv, Israel: **General** discussion
- February 24 – 25, 2023 Sao Paulo, Brazil: **Placebo**
- September 21 – 22, 2023 in Copenhagen, Denmark: **New clinical trial design**

  IFAPP President Varvara Baroutsou invited
- 30 November – 1 December 2023 in Tokyo, Japan: **Disaster** settings
- Jan 18, 19, 2024 Vatican City: Research in **resource-poor** settings

https://www.wma.net/events-post/wma-conference-on-the-revision-of-the-declaration-of-helsinki-research-in-resource-poor-settings/

- Feb 18, 19, 2024 Johannesburg: **Vulnerability**

https://www.wma.net/events-post/wma-regional-meeting-in-africa-on-the-revision-of-the-declaration-of-helsinki/

- May 14, 15, 2024 Munich, Germany: Research with **vulnerable** people

https://www.wma.net/events-post/research-with-vulnerable-people-a-targeted-interdisciplinary-discussion-within-the-scope-of-the-wma-declaration-of-helsinki-revision/

- August 15-16, 2024 Washington DC, US: **Advocacy and Communication**

https://www.wma.net/events-post/wma-declaration-of-helsinki-revision-advocacy-and-communication/

IFAPP Ethics Working Group Chieko Kurihara invited

- October 16-19, 2024 Helsinki, Finland, WMA General Assembly: **Adoption**

Linking the DoH and DoT: IFAPP EWG

PERSPECTIVE article

Front. Pharmacol., 29 October 2020 | https://doi.org/10.3389/fphar.2020.579714

Check for updates

Linking the Declarations of Helsinki and of Taipei: Critical Challenges of Future-Oriented Research Ethics

Chieko Kurihara[1*], Varvara Baroutsou[2], Sander Becker[3], Johan Brun[4], Brigitte Franke-Bray[5], Roberto Carlesi[6], Anthony Chan[7], Luis Francisco Collia[8], Peter Kleist[9], Luís Filipe Laranjeira[10], Kotone Matsuyama[11], Shehla Naseem[12], Johanna Schenk[13], Honorio Silva[14] and Sandor Kerpel-Fronius[15] on behalf of Working Group on Ethics of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine

Kurihara C, Baroutsou V, Becker S, Brun J, Franke-Bray B, Carlesi R, Chan A, Collia 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

WMA Declaration of Taipei (DoT) complementing Declaration of Helsinki (DoH)

The essential requirements of the DoT

1) Items of information for obtaining "**valid**" **consent** when data/material are collected in a Health Database (HDB) or Biobank (BB) are defined including, e.g., the purpose of the HDB/BB; returning results including incidental findings;

2) Robust **governance** process of HDB and BB are defined including, e.g., documentation; traceability; arrangement of ownership change or closure; privacy protection and discrimination prevention; Material Transfer Agreement (MTA), all of which should be informed to the candidate donor of the data or material

WMA Declaration of Taipei
https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/
Summarized in: Kurihara C, et al. Front. Pharmacol., 29 October 2020
https://doi.org/10.3389/fphar.2020.579714

IFAPP's activity under the MoU with WMA
(1) Data-driven Research

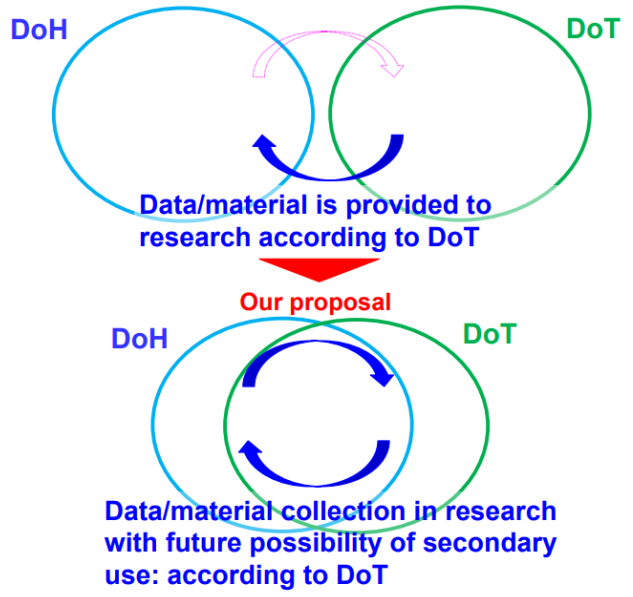
We adhere to the DoH for research.

We adhere to the Declaration of Taipei (DoT) for data collection, secondary use.

Recommendations:

1. Connection between DoH and DoT

Data and/or biological material collected as a part of the research, which may be used for secondary analysis, should be in the scope of DoT, and this should be clarified in the "**General Principles**" of the DoH.



2. Ethical approval and consent for secondary use

- If the data/samples collected in research is anticipated to be used for other purposes after the research (="secondary use"), it should be included in the research protocol for ethical approval.
- Informed consent should be obtained separately.
- This should be clarified by revisions of **paragraphs 22 (protocol) and 26 (informed consent).**

Protocol title
Informed Consent Form

Participation in clinical trial

Signature **Date**

Secondary use of Data/Sample

Signature **Date**

Scientific paper in peer-reviewed journal

Linking the Declarations of Helsinki and of Taipei: Critical Challenges of Future-Oriented Research Ethics. *Front. Pharmacol*. Oct 2020. doi: 10.3389/fphar.2020.579714

https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2020.579714/full

Infographics and commentary in IFAPP's journal

IFAPP TODAY 2021; Dec 2021 No. 19: p.13-15
https://ifapp.org/static/uploads/2021/12/IFAPP-TODAY-19-2021.pdf

Poster presentation with infographics for the paper
http://cont.o.oo7.jp/50_1/IFAPPToday-DoHDoT-Poster-English.pdf

IFAPP's activity under the MoU with WMA
(2) Proposal for the entire construction of the DoH

IFAPP's official recommendation submitted to the WMA in 2019, published in IFAPP's journal

Kurihara C. **IFAPP Recommendations for the Revision of the Declaration of Helsinki, Version 2013**. *IFAPP TODAY*. 2022; Jan (20): 3-7. https://ifapp.org/static/uploads/2022/01/IFAPP-TODAY-20-2022.pdf

Reconstructed and published in peer-reviewed journal, this year.

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. 2024 Apr 2;11:1360653. doi: 10.3389/fmed.2024.1360653. PMID: 38628806; PMCID: PMC11019506.

IFAPP's activity under the MoU with WMA

(3) Inviting WMA (Drs Resneck, Kloiber, Tsai, Berggreen Høj) at IFAPP regional mtgs

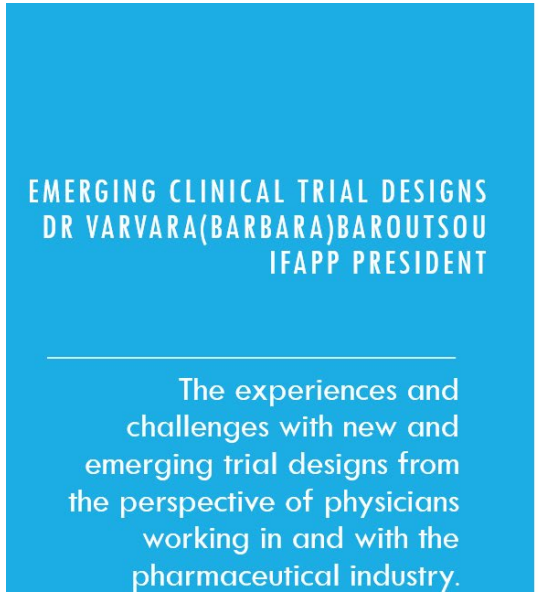
IFAPP President (Dr Baroutsou) invited WMA regional mtg for DoH

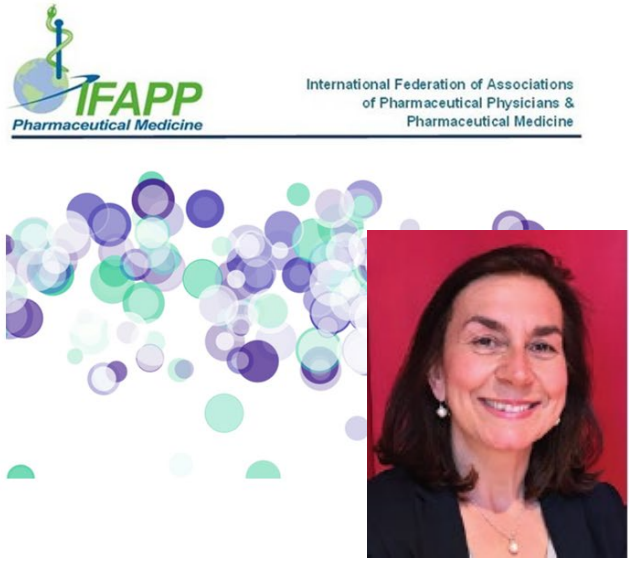
Future revision of the Declaration of Helsinki: Dialogue with WMA in Athens. *IFAPP TODAY.* 2022; Nov/Dec (29) : 5-8. https://ifapp.org/static/uploads/2022/11/IFAPP-TODAY-29-2022.pdf

Next Revision of the Declaration of Helsinki: Meetings of the WMA and IFAPP. *IFAPP TODAY.* 2023; May (34):8-12. https://ifapp.org/static/uploads/2023/05/IFAPP-TODAY-34-2023.pdf

Discussion in Amsterdam on Data-driven Research and the WMA Declaration of Helsinki. *IFAPP TODAY.* 2023; Sept (37):5-9. https://ifapp.org/static/uploads/2023/09/IFAPP-TODAY-SEPTEMBER-2023-37.pdf

IFAPP President invited WMA Regional meeting in Copenhagen on Emerging Clinical Trial Design





DoH Public Comment Participation (1st and 2nd wave)

World Medical Association Declaration of Helsinki 2024 Revision: Phase 1 Public Comment Document

Overview

Public Comment Period 1: Proposed Edits to Date

Regional meetings held to date have so far focused on the following themes:

- Technological advancements, especially related to large-scale datasets, machine learning, artificial intelligence, and associated risks of privacy loss
- Use of placebo, no intervention, or less effective interventions in research trials
- Emerging and non-traditional trial designs
- Pandemics and other emergencies

A series of other issues arose at these regional discussions and workgroup meetings:

- Inclusive language that honors the rights, agency, and importance of participants in medical research.
- Recognition that human medical research participants include patients and healthy volunteers
- Consent for collection, storage, reidentification, and reuse of data, and alignment with the Declaration of Taipei
- Adequate resources, education, and experience for ethics review committees
- Importance of scientifically sound design to avoid research waste
- Importance of social value (including individual and public health) as additional purposes of conducting medical research
- Consideration of environmental impacts of medical research
- Interdisciplinary team-based research and whether the protection afforded by the Declaration's principles must extend to all medical research regardless of who is conducti
- Recognition of electronic methods of documen
- Responsibility to attempt to honor prior expres sought from a legally authorized representative

Declaration of Helsinki Public Comment Period Two

COMMENTING ORGANIZATION (if applicable):

Members of the Ethics Working Group (EWG) of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)

POLICY BRIEF article

Front. Med., 02 April 2024

Sec. Regulatory Science

Volume 11 - 2024 | https://doi.org/10.3389/fmed.2024.1360653

Declaration of Helsinki: ethical norm in pursuit of common global goals

 Chieko Kurihara[1,2*]  Sandor Kerpel-Fronius[2,3]  Sander Becker[2,4]  Anthony Chan[2,5]

 Yasmin Nagaty[2,6] Shehla Naseem[2,7]  Johanna Schenk[2,8]  Kotone Matsuyama[2,9]  Varvara Baroutsou[2]

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[4] Consultants in Pharmaceutical Medicine, Dover Heights, NSW, Australia
[5] Pfizer Healthcare Ireland, Dublin, Ireland
[6] The Middle East Association of Pharmaceutical Medicine Professionals, Cairo, Egypt
[7] Academic and Research College of Family Medicine, Karachi, Pakistan
[8] PPH plus GmbH & Co. KG, Hochheim am Main, Germany
[9] Department of Health Policy and Management, Nippon Medical School, Tokyo, Japan

The World Medical Association's Declaration of Helsinki is in the process of being revised. The following amendments are recommended to be incorporated in pursuit of the common goal of promoting health for all. 1. Data-driven research that facilitates broad informed consent and dynamic consent, assuring participant's rights, and the sharing of individual participant data (IPD) and research results to promote open science and generate social value. 2. Risk minimisation in a placebo-controlled study and post-trial access to the best-proven interventions for all who need them. 3. A future-oriented research framework for co-creation with all the relevant stakeholders.

Next Issue; ELSI with new emerging technology

Data Privacy Law

The New Emerging Technology

Clarification of choices (patternism)

Patient Public Involvement/ Education

Use of genetic analysis tools

- Genomic ELSI
  1. Genomic data ethical issues related to the subject itself
  2. Genomic ethical issues related to relevance, systemic issues, etc. (stakeholder, training, etc.)
  3. Ethical issues related to special design or use of
  4. Local regulations (comparison with other countries)
  5. Ethical issues due to culture, custom, and medical environment
  6. issues due to language differences
  7. Genomic editing technology: newly emerging the ELSI (artificial nucleotide insertion)
  8. RWD with genomic information (use, privacy, etc.)
  9. Medical insurance (private company)
  10. Relatively high cost of the genomic treatment
  11. The privilege for the intellectual property of the genetic testing