Proceedings

グローバル研究倫理と意義ある参画へのコンセンサスに向けた3回連続国際会議*

グローバル研究倫理と意義ある患者・市民参画：コンセンサス形成－準備会議及びPart 2

主催：ブラジル生命倫理学会，医療開発基盤研究所（Ji4pe）
後援：日本医学哲学・倫理学会，国際製薬医学会，日本製薬医学会，Juju Barbosa
協力：臨床評価刊行会，生命倫理政策研究所，臨床研究リスク管理研究会
プロデュース：国立成育医療研究センター（9月13日）
2025年8月25日㈪ オンライン・9月13日㈯ ハイブリッド（オンライン／東京）

グローバル研究倫理の変革：ヘルシンキ宣言2024年改訂における患者・市民参画と脆弱性に関するダイナミックな考察

主催：日本医学哲学・倫理学会 第２回国際大会
セッション・プロデュース：国立成育医療研究センター
2025年9月15日㈪ 神奈川大学みなとみらいキャンパス

Three Sequential Meetings: Consensus for Global Research Ethics and Meaningful Engagement

(See detail in the next page.)

Global Research Ethics and Meaningful Patient and Public Involvement: Consensus Development－Preliminary web conference and Part 2

Organised by the Brazilian Society of Bioethics and Ji4pe
Supported by Japanese Association for Philosophical and Ethical Researches in Medicine (JAPERM), JAPhMed, IFAPP and Juju Barbosa;
Produced by the National Center for Child Health and Development (September 13)
25 August, Monday (online) & 13 September, Saturday (Hybrid: online / Tokyo), 2025

Transformation of the global research ethics: the 2024 revision of the Declaration of Helsinki to promote patient engagement and dynamic consideration on vulnerability

Organized by JAPERM
Session Produced by the National Center for Child Health and Development
15 September, Monday, 2025, at Kanagawa University, Minato Mirai Campus, Yokohama, Japan

Three Sequential Meetings: Consensus for Global Research Ethics and Meaningful Engagement

Global Research Ethics and Meaningful Patient and Public Involvement: Consensus Development– Preliminary web conference and Part 2

Organised by:
The Brazilian Society of Bioethics (SBB)
Japanese Institute for Public Engagement (Ji4pe)
Supported by:
Japanese Association for Philosophical and Ethical Researches in Medicine (JAPERM)
The Japanese Association of Pharmaceutical Medicine (JAPhMed)
International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)
Juju Barbosa
Cooperation:
Clinical Evaluation
Center for Bioethics Policy Study
Clinical Research Risk Management Study Group
Produced by:
The National Center for Child Health and Development (September 13)
25 August, Monday (online) & 13 September, Saturday (Hybrid: online / Tokyo), 2025

Transformation of the global research ethics: the 2024 revision of the Declaration of Helsinki to promote patient engagement and dynamic consideration on vulnerability

Organized by:
The Japanese Association for Philosophical and Ethical Researches in Medicine (JAPERM) Second International Conference 2025, Open Symposium
Session Produced by:
The National Center for Child Health and Development
15 September, Monday, 2025, at Kanagawa University, Minato Mirai Campus, Yokohama, Japan

Abstract

In advance of the 2nd International Symposium of the Japanese Association for Philosophical and Ethical Researches in Medicine (JAPERM) on 15 September 2025, an online symposium was held on 25 August co-organised by the Brazilian Society for Bioethics (SBB) and the Japanese Institute for Public Engagement (Ji4pe) to support consensus development for "Global Research Ethics Norm" based on "Patient Public Declaration of Research Ethics" originated by a patient and public group, and "Meaningful Engagement", considering existing documents, most recently a new paragraph in the 2024 revision of the World Medical Association's Declaration of Helsinki.

The outcome of the 25 August online symposium, where patients, public and professionals gave presentations, was bridged to the hybrid (online & in-person in Tokyo) meeting on 13 September with invited speakers Prof. Dirceu Greco (Immediate-past President of the SBB) and Dr. Varvara Baroutsou (Immediate-Past President of the IFAPP), broadcasted worldwide.

In addition, the topics were further discussed on 15 September at JAPERM symposium in Yokohama, and finally "The Statement for Global Research Ethics Norm and Meaningful Engagement: GREEN Statement" was issued on 17 September 2025, calling for more signatories until the end of October, and addressed to the international organisations, engaged in development of international research ethics norms, such as United Nations (UNESCO, WHO), CIOMS and WMA.

Key words

research ethics norm, meaningful engagement, patient and public involvement, global ethics, the Declaration of Helsinki

Rinsho Hyoka（*Clinical Evaluation*）. 2025；53(2)：237-80.

抄録

2025年9月15日に開催された日本医学哲学・倫理学会第2回国際大会に先立ち，8月25日に患者・市民が主導した『患者・市民の研究倫理宣言』に基づく「グローバル研究倫理規範」及び，世界医師会『ヘルシンキ宣言』2024年改訂を含む既存の文書に基づく「意義ある参画」について，新たなコンセンサスの形成を支援するブラジル生命倫理学会と医療開発基盤研究所（Ji4pe）の共催でオンライン会議を開催し，続いて9月13日に来日中の国際製薬医学会（IFAPP）前会長Dr. Varvara Baroutsou，ブラジル生命倫理学会元会長Prof. Dirceu Grecoとともにハイブリッド会議（オンライン＋現地・東京）を開催，そして9月15日には両氏を招いて日本医学哲学・倫理学会第2回国際大会（横浜）を行った．これらの成果は9月17日に『グローバル研究倫理規範と意義ある参画に向けた声明：GREEN声明』として発信され，10月末までさらに賛同者を募り，国際研究倫理規範作成に携わる国際機関である国際連合（UNESCO，WHO），国際医学団体協議会（CIOMS），世界医師会（WMA）に届けられた．

キーワード

研究倫理規範，意義ある参画，患者・市民参画，グローバル倫理，ヘルシンキ宣言

＊ 本稿は表記主催団体による講演会のProceedingsであり，使用言語はすべて英語であったが，日本人の講演は日本語訳，日本人以外の講演は英語で掲載した．8月25日・9月13日の会議の録画及び関係資料は下記の本誌websiteより閲覧できる．全ての発表は，特に出典が明記されない限りは発表者の個人的見解である．なお，3回連続会議を経て発表された『GREEN声明』は計画に従って国際機関に提出され，本号印刷版及び本誌websiteに掲載されている．
https://cont.o.oo7.jp/53_2/53_2contents.html
All the lectures and discussions were in English. In this publication, the parts of Japanese speakers are translated in Japanese and others are in English. Video-recording of the meetings in August 25 and September 12 are available at the website of this journal issue, below. All of presentations are speakers' versional view unless specific reference is provided. The GREEN Statement, developed following three consecutive meetings, has been submitted to international organisations as planned and is published in the website of this journal issue.
https://cont.o.oo7.jp/53_2/53_2contents_e.html

グローバル研究倫理と意義ある患者・市民参画：コンセンサス形成－準備会議

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2025年8月25日㈪ オンライン

Global Research Ethics and Meaningful Patient and Public Involvement: Consensus Development－Preliminary web conference

Organized by:
The Brazilian Society of Bioethics (SBB)
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Supported by:
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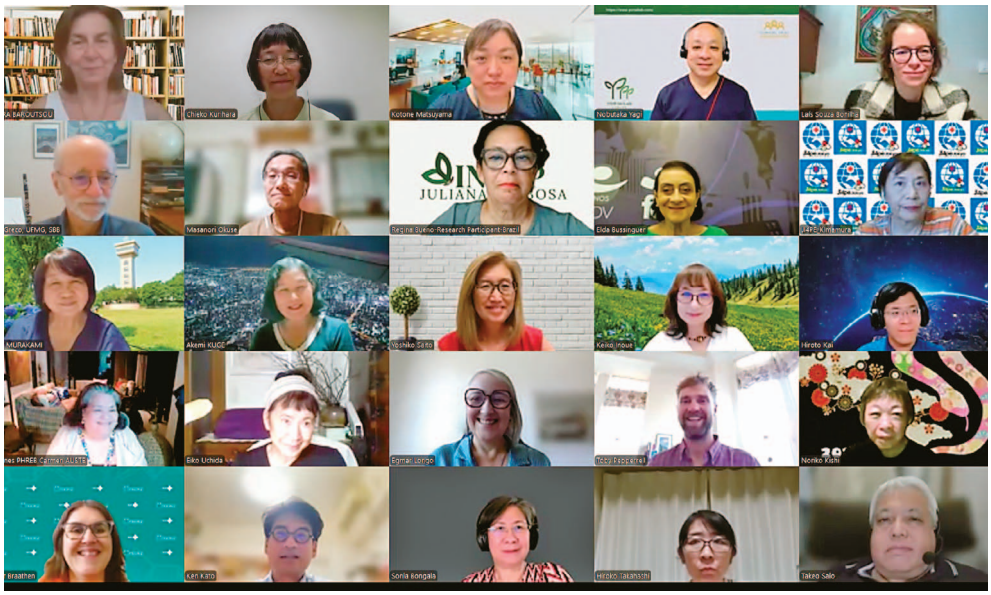
Juju Barbosa
Cooperation: Clinical Evaluation; Center for Bioethics Policy Study
Clinical Research Risk Management Study Group
25 August, Monday, 2025 (online)



297頁の*IFAPP TODAY*記事翻訳の写真キャプションを参照.
See explanation beside the photo in the page 6 of the article to introduce the result of this conference in *IFAPP TODAY*. 2025; No. 57: 4-6.:
https://ifapp.org/wp-content/uploads/2025/09/IFAPP_TODAY_57_September_2025.pdf
Video, presentations and other materials:
http://cont.o.oo7.jp/sympo/GREandME.pdf

開会の辞
Welcome remarks from organisers

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

今村　恭子

医療開発基盤研究所（Ji4pe）代表理事；国際製薬医学会（IFAPP）元会長

Kyoko Imamura, MD, PhD, President, the Japanese Institute for Public Engagement (Ji4pe), Japan; Former president, IFAPP

Elda Coelho Azevedo Bussinguer

Brazilian Society of Bioethics is very much pleased to be here to co-organize this special important meeting with Japanese Institute for Public Engagement (Ji4pe), sharing the situations important for all of us. Currently, the Brazilian system of ethics in research, already well-established, faces difficulties due to a strong backlash against the existing guidelines. Not limited to such situation in Brazil, for the global situation of research ethics, patient participation is especially important. We emphasize that there are many reasons to promote emancipation and participation of patient and public to contribute to improvement of research ethics. We regard this project with Japanese groups and international collaborators to work together for global research ethics norms which help all of us to reenforce human rights and bioethics in health research.

今村　恭子

医療開発基盤研究所（Ji4pe）は，私が東京大学大学院薬学系研究科で社会連携講座の特任教授を務めていた折の活動として2020年に設立しました．当時，いかに患者参画が日本で実現できるかを検討していましたが，幸運なことに多くの患者と市民グループが参加し，医薬品開発の方法論や医療について学びを進めてきました．残念ながら日本では研究対象者保護の法令がなく，インフォームド・コンセントの重要性が人々の常識となるために，市民，アカデミア，企業，規制当局などすべての関係者が共有できる教育システムを構築してきました．今回のように国を超えて共通のアジェンダを議論することはとても重要です．Ji4peの生命倫理ワーキンググループはとても意欲的で，このグループが作成した『患者・市民の研究倫理宣言』が日本とブラジル，そして世界の患者・市民参画の推進に貢献することを期待します．

Ji4peではホームページで紹介のとおりいくつかの教育コースがあり，患者・市民参画のエキスパートを育成しています．専門家の教育，コンサルティング，子ども向けの漫画などもあります．世界医師会『ヘルシンキ宣言』（DoH）についての学びから出発した生命倫理ワーキンググループは最もアクティブなメンバーですが，他にファンドレイジング，医療政策のワーキンググループもあります．DoHはとても重要ですが，医師によって医師向けに作成されたものです．そこで『患者・市民の研究倫理宣言』では，患者・市民の手によって研究倫理規範が作成される必要があるという動機付けをもって活動し，発表しました．今後のすべての国の状況を改善することにつながることを願っています．

日本からの発表

グローバル研究倫理に向けた「意義ある参画」：患者・市民の研究倫理宣言

Meaningful Engagement toward Global Research Ethics: Patient Public Declaration of Research Ethics

甲斐　寛人，齊藤　嘉子，村上　利枝，久下　明美，
岸　　紀子，井上　恵子，内田　絵子

医療開発基盤研究所（Ji4pe）生命倫理ワーキンググループ

Hiroto Kai, Yoshiko Saito, Toshie Murakami, Akemi Kuge, Noriko Kishi, Keiko Inoue, Eiko Uchida
Bioethics Working Group, Japanese Institute for Publica Engagement (Ji4pe), Japan

Ji4pe生命倫理ワーキンググループは2020年に世界医師会『ヘルシンキ宣言』について学ぶことからスタートして，『わたしたちのWMAヘルシンキ宣言』[1]というタイトルで，(1)『ヘルシンキ宣言』(DoH) 日本医師会訳，(2)私たち患者・市民の言葉によるDoH条文リライト，(3)私たちの意見，という3層構造からなる成果物を2024年に発表しましたが，それに先立って，2023年には (3)「意見」の部分をまとめて英文論文を発表しました[2]．この私たちの「意見」の部分を『患者・市民の研究倫理宣言』[3]に構成しなおして，2024年10月，DoH2024年版採択直前に英語版を発表し世界医師会にも届けました．

近年の先端技術の開発，人工知能，ゲノム編集，iPS細胞，脳オルガノイドといった技術の臨床応用に対して私たちは様々な期待と懸念を抱いており，だからこそ患者・市民参画は必要不可欠です．

私たちのグローバル研究倫理規範に向けた意見は以下のようです．

- 研究対象者，社会に対する影響をグローバルな文脈や未来世代・環境への影響も考慮し，差別やスティグマ化に結びつくことを回避し，SDGsに向けるためにも研究開発の早期段階からの患者・市民参画が必要．
- グローバル研究倫理規範は平易な言葉で記述され，生きている人だけではなく受精胚，胎児，死者に対する敬意も明確にし，すべてのプロセスに患者・市民が参画すること，多職種協働・共同意思決定を推進し，倫理審査委員会の多様性と一般市民参画を確保し，身寄りのない人も含めた弱い立場の人々のアドボケートを進めるため，すべての関係者が参画して作成する．
- 「私たち抜きに，私たちのことを決めないで！」(Nothing about us, without us) は，国連の障害者権利条約 (2006年) 締結に向けたスローガンとして知られるが，障害者だけではなく，いつでも「弱者」となる可能性のある私たちすべての心の叫びである．

このため私たちの『患者・市民の研究倫理宣言』がグローバル研究倫理規範に取り入れられることを期待しています．

日本からの発表

患者にとっての「意義ある」参画とは？

What does “meaningful” engagement mean to patients?

奥瀬　正紀

一般社団法人日本乾癬性疾患協会

Masanori Okuse, Japanese Association for Psoriatic Disease, Japan

『ヘルシンキ宣言』2024年改訂について患者が期待するのは，研究の透明性と信頼性の向上，研究対象者保護の強化，研究結果の社会還元，患者の声を政策決定やヘルスケアシステムに反映させる，といったことです．「意義ある」参画とは，形式だけではなく，患者の権利，役割，責任を認め，研究のあらゆる段階で積極的に参加することです．

患者ができることは，経験を共有し，研究や政策立案に参加し，自らの医療情報リテラシーを向上し，他の患者と連携し，研究結果の活用を促進することです．私たちの「意義ある」参画の2つの実例を挙げます．

(1) Research Project on Psoriasis Value Outcome Set (PsoVOS)

患者にとっての「価値」は健康アウトカムです．乾癬は重篤かつ複雑で生涯続く疾患であり，全人的ケアが必要です．グローバルな患者組織であるIFPA (International Federation of Psoriasis Associations) は，自分たちにとって重要な価値に基づくアウトカムについてのコンセンサスを形成するプロジェクトに参加しています．

(2) Global Research on the Impact of Diseases (GRIDD)

GRIDDプロジェクトでは，カーディフ大学，ハンブルグエッペンドルフ大学医療センター，グローバルスキン（皮膚疾患患者団体国際連合）との共同研究としてPRIDD (Patient-Reported Impact of Dermatological Diseases) を開発しました．これは患者があらゆる段階で参加して開発され，妥当性が検証された皮膚科患者報告アウトカム指標です．

利益相反

奥瀬個人には開示すべき利益相反はないが，所属団体は以下の資金援助を受けている．AbbVie, Almirall*, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Fuji Pharma**, Johnson & Johnson, Leo Pharma, Maruho**, Novartis, Pfizer*, Sun Pharma**, Takeda*, Torii**, and UCB.

*：Only to International Federation of Psoriasis Associations

**：Only to Japanese Association for Psoriatic Disease

日本からの発表

意義ある参画とは？

What is “meaningful” engagement?

八木　伸高

一般社団法人 YORIAILab 代表理事；一般社団法人 PPI JAPAN 運営委員；
日本ベーリンガーインゲルハイム株式会社 シニアペイシェントエンゲージメントメディカルアドバイザー

Nobutaka Yagi, Representative Director, YORIAILab; Steering Committee, PPI JAPAN;
Sr Patient Engagement Med Advisor, Nippon Boehringer Ingelheim, Japan

1. YORIAILabの活動：プロセスとアウトカム

YORIAILabは，治験アンバサダー・プロジェクトを運用する非営利の法人（NPO）です．患者・市民の意義ある参画のためのプラットフォームで様々なステークホルダーが協働しヘルスケアにおける課題を検討しています．特に，患者視点を取り入れた臨床試験エコシステムと平易な言葉（レイランゲッジ）によるコミュニケーションの促進，ペイシェントエクスペリエンスデータ（患者としての経験を伝えるデータ：PED）のシステマティックな構築と活用促進に取り組んでいます．

様々なバックグラウンドの方々が包摂的に持続可能な参画をできるように，ベネフィットの公平で互恵的な共有，アクションに結びつく学びの場の共有や，患者とコミュニティのエンパワメントのプロセスを通じて，その経験をヘルスケアの様々なステージでの意思決定に活かし，その価値を社会還元することをアウトカムとして目指しています．

2.「意義ある参画」を推進する臨床試験アンバサダー・プロジェクト

臨床試験アンバサダー・プロジェクトは2021年から開始されたオープン・イノベーション・イニシアチブです．患者・市民が参加する教育プログラムで，そこでは医薬品開発や臨床試験に関する様々な課題を検討します．“Made with Patients Awards 2025 finalist”として世界的にも認知されるようになりました．

「臨床試験レイサマリー」のプロジェクトは，患者を含む様々なステークホルダーの参画によって，日本では初めて，臨床試験結果のレイサマリーのためのガイダンスを作成しました．

PEDパイロット・プロジェクトでは，PEDを具体的に活用するためのアプローチを患者との協働により取りまとめています．これは患者のニーズや優先事項をある特定の治療領域の治療ガイドラインに取り入れ，医療の意思決定に役立つものとなるよう妥当性を検証するプロジェクトです．

これらの活動により，日本における患者・市民参画を推進しています．

Presentation from Brazil

CNS/CONEP's coordination involving patient/participants groups

Laís 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), Brazil

Brazil is a wealthy country, however, its vast disparities necessitate public enlightenment in research. National Commission on Ethics in Research (CONEP) is a part of Commission of the National Health Council (CNS). This system of CNS, composed of 18 entities including CONEP, is guaranteed by the 1998 Federal Constitution. The CNS created the CONEP by resolution 196/1998, succeeded by the Resolution 486/2012, which established regional research ethics committees (CEPs). The CEP/CONEP System is responsible for the ethical supervision of all research projects involving humans in Brazil, as the highest social oversight body.

In Brazil, currently there are 905 CEPs. CONEP's role is to coordinate these CEPs. CONEP receives questions and complaints from CEPs, researchers, and research participants. In recent years, questions and complaints from research participants have been increasing.

Before and after COVID-19 the number of protocols analyzed by CONEP is around 4,000 per year (4,291 in 2019, 3,802 in 2022), whereas during COVID-19 it was 8,792 in 2020 and 7,298 in 2021.

CONEP is an independent research review body established by statute, but recent legislative amendments threaten to undermine this independence. We are fighting to preserve the current system.

Presentation from Brazil

Global Research Ethics: Proposal for Patient and Public Directives on Research Ethics

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; Past Vice-Chair of the UNESCO International Bioethics Committee; Associate Member of the World Medical Association

1. Background/Rationale

The rationale for "Participatory Research" has already been established. It "*focuses on a process of sequential reflection and action, carried out with and by local people rather than on them. Local knowledge and perspectives are not only acknowledged but form the basis for research and planning*" [4]. And stakeholder engagement refers to processes through which trial funders, sponsors, and implementers build transparent, meaningful, collaborative and mutually beneficial relationships with interested or affected individuals, groups of individuals, or organizations, with the ultimate goal of shaping research collectively [5]. "Emancipation" [6] involves the recognition of independent capacity or the ability to act according to one's own will—the ability to think, reflect, and act in the world to transform it. It demands that scientific research be organized in such a way as to not only protect the individual from harm, but also to promote their autonomy, guarantee social justice and ensure that science is, in fact, an instrument of emancipation for all. The fight for equality in research, therefore, is the ongoing search for a future where science and ethics walk side by side, respecting and valuing each participant as a subject with full rights.

2. Participants' rights and access to care: existing documents

Existing documents already demonstrate participants' rights to access care. To achieve this, the participation of all the interested parties is a prerequisiste, including, most importantly, study participants and their community.

(1) 2005 UNESCO Declaration on Bioethics and Human Rights [7]

UNESCO's Universal Declaration on Bioethics and Human Rights defines as one of its objectives "*to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries*" (Article 2).

(2) 2011 UNAIDS Good participatory practice– guidelines for biomedical HIV prevention trials [5]

UNAIDS states that "*...stakeholders include trial participants and other community stakeholders as well as a broader range of national and international stakeholders*."

(3) 2016 CIOMS Guidelines for Health-related Research [8]

CIOMS Guidelines states that "*Scientific and social value cannot legitimate subjecting study participants or host communities to mistreatment, or injustice*" (Guideline 1); and also require sponsors and researchers "*to consult with and engage communities in making plans for any intervention or product developed avail-*

able, including the responsibilities of all relevant stakeholders." (Guideline 2)

(4) 2016 WHO Good Participatory Practice Guidelines [9)]

The WHO's Good participatory practice guidelines define a subset of stakeholders that can be described as community stakeholders. These are individuals and groups that ultimately represent the interests of people who would be recruited to participate in a trial, others locally affected by the conduct of a trial, and those who will be affected by the research results, including lay residents of a local area, health professionals, service providers, and local policymakers.

(5) 2024 WMA Declaration of Helsinki [10)]

Building on these existing documents, the World Medical Association's Declaration of Helsinki (DoH) 2024 revision included for the first time a principle to promote engagement of research participants and their community in all the processes of research.

(6) 2024 Helsinki Statement [11)]

Despite the improvements incorporated into the 2024 DoH, some important items were rejected during the revision process. Among these, the "social value" of research should be a fundamental objective; the higher standards present in the 2000 version of the DoH, which allow placebo-controlled trials only when there is no proven intervention, and the guarantee of post-trial access to effective and safe study intervention for those who still need it, should be restored. To this end, we issued the "Helsinki Statement" which included 10 improvements to the 2024 DoH and 5 points of disagreement, including the absence issues of social value, the restrictions on placebo use and insufficient guarantee of post-trial access. The statement was published one day before the adoption of 2024 DoH. Through global discussions via virtual meetings and e-mail, 125 individual signatories from 24 countries, primarily from the Global South and Asia, were included in the publication of this statement.

(7) 2024 Patient Public Declaration of Research Ethics [3)]

At the same time as the above discussion, the Japanese patient group, Ji4pe Bioethics Working Group, issued its Patient Public Declaration on Research Ethics. It clarified the importance of patient and public participation in the process of developing global research ethics norms.

(8) 2024 Brasil Instituto Nacional de Proteção de Participantes de Pesquisa Juju Barbosa (National Institute of Research Participants Juju Barbosa) [12)]

With the same objectives as its Japanese counterparts, "Brasil Instituto Nacional de Proteção de Participantes de Pesquisa Juju Barbosa" (National Institute of Research Participants Juju Barbosa) was created in May 2024. Its objectives include contributing to the emancipation of research participants and the unequivocal defense of their rights, as well as the inclusion of the social value of research, and the improvement of ethical and legal standards for research conducted in Brazil. This emancipation will occur through the exercise of protagonism and the relevance of societal control, according to the Brazilian CEP/CONEP research system and advocate that innovations in research, when safe and effective, be incorporated into the Brazilian Unified Health System (SUS).

3. Conclusion/Perspectives

Integrating the above-mentioned background and discussions in existing documents, we propose the necessary items for "Meaningful Patient and Public Engagement" as below (the texts were adjusted for the final

version in the GREEN Statement [13]).

1. Establish a collaborative partnership that recognises structural inequity and strives to overcome it, ensuring access to the benefits of research and promoting the interests of disadvantaged individuals (UNAIDS 2021 [14]).

2. Establish effective and responsible participation, (e.g., decision-making rights), through systematic educational programmes.

3. Advocate for the participation of people with difficulties in making autonomous decisions.

4. Ensure the diversity of participants engaged in policy making, through open and fair recruitment.

Presentation from Brazil

Relevance of creating an association for the protection of research participants

Regina Bueno*, AGANIN (Association of Gays and Friends of Nova Iguaçu, Mesquita and Rio de Janeiro. Pastoral da AID), Brazil

Jose Silvino Gonçalves dos Santos, CAPDEVER (Afro Center for the Promotion and Defense of Life), Brazil

Ezequiel Ramin, Pastoral Ministry of the Catholic Church, Brazil

Dirceu Greco, School of Medicine - Federal University of Minas Gerais (UFMG), Brazil

Ana Lucia Paduello, Rheumatic Patient Support Group Brazil, Brazil

All representing INPP Juliana Barbosa Research Participant Protection Institute, Brazil

* Presentation at the webinar

The CEP/CONEP System (Research Ethics Committee/National Research Ethics Commission) in Brazil ensures the defense of the rights and interests of research participants, with more than 16,000 people involved in ethical analyses. Although resolutions 466/2012 and 510/2016 of the National Health System (CNS), in addition to 706/2023, which guides the accreditation of CEPs in the System contributing to the to the social value of research, CONEP has received a growing number of complaints from research participants and family members. In this context, Juliana Barbosa Research Participant Protection Institute was created in May 2024 with the mission of defending the rights of research participants and their representatives in the community spaces necessary to maintain ethics in research and bioethical care for this population [12].

Our purposes and trajectory to this goal can be described as:

- ✓ Promoting the emancipation of research participants by providing information about participation in research, their rights as participants, addressing questions and complaints, and contributing to the strengthening of this group.
- ✓ Clearly inform its members about what it means to participate in scientific and/or technological research in the health field;
- ✓ Provide training on understanding the process of free consent and/or assent and of other instruments necessary to participate in clinical research.
- ✓ Participate in meetings called by the Association seeking the best and good practices that should be exercised among its members, with respect and decorum;
- ✓ Exchange knowledge and information about the CEP/CONEP system and the studies in which you can participate;
- ✓ Promote, in collaboration with other members of the Association and the CEP/CONEP System, specific issues related to the interests and rights of research participants;
- ✓ Maintain the confidentiality of matters designated and agreed upon among the Association's members,

maintaining transparency and a commitment to the collective to decline, and declare any interest in the matter to be discussed;

- ✓ Ensure that members have a space for active listening and guidance on any questions they may have about the research in which they wish to participate;
- ✓ Ensure that the Association is a democratic and participatory space that protects research participants, ensuring their personal, political, social, and economic rights in contributing to the social purpose set forth in this instrument; and
- ✓ Encourage the protagonism of its members, respecting their individual characteristics.

In addition, we clarify the rights of research participants as follows:

1) Receive study information in an accessible and understandable manner;
2) Have the opportunity to clarify any questions;
3) Have the time necessary to make an independent and informed decision;
4) The right to refuse to participate in the study;
5) The right to withdraw consent at any stage of the research;
6) The right to withdraw consent for the use and storage of biological material;
7) Receive assistance (full and immediate) and compensation for research-related damages, free of charge;
8) Receive reimbursement for expenses (including expenses for companions);
9) Have access to the results of tests performed during the study;
10) Request the removal of genetic data from databases where they are stored;
11) Have unlimited free post-study access to safe and effective research products (the new Brazilian Law 14.874/24 eliminates unlimited access to post-study medications);
12) Have free access to the chosen contraceptive method (when applicable);
13) Receive free genetic counseling (when applicable);
14) Have data confidentiality guaranteed;
15) Privacy guaranteed;
16) Receive a copy of the Informed Consent or Assent Form (signed and initialed by the research participant and the researcher).

In summary, expanding emancipation of research participants in this way would contribute to solving current challenges of research, fostering good research participatory practice among participants, and ultimately, defending and improving Brazil's Unified Health System (SUS.)

Presentation from Brazil

Experience with meaningful participant involvement in research

Egmar Longo, PhD, Physiotherapist, Federal University of Paraíba, Brazil

1. Patient and Public Involvement (PPI)

Process of co-creating decisions in partnership with patients and/or the public will ensure that equity and social justice guide both priorities and outcomes. PPI would embrace whole the research cycle: define research question; design study; recruitment and consent; data collection; analysis; implementation. We have to have every voice, at every decision in research cycle. This is according to the UK Standards for Public Involvement (NIHR 2019), as we are collaborating with some institutions in Europe, including United Kingdom. This is important aspect of research governance. We work together, keeping important communication between research team and participants, in lay language. UK Standards also promote inclusive opportunities in terms of gender, ethnicity, etc. We also need support to participants, and promote learning, to provide people skill to free to talk in free space. Our team in Brazil is currently translating the UK Standards into Brazilian Portuguese, with formal approval from NIHR, to promote broader accessibility and support the expansion of PPI practices across Latin America.

2. PPI Training Initiatives

We prepared a series of open-access e-books on Patient and Public Involvement (PPI) to disseminate knowledge and to help build a national culture of involvement in Brazil. These materials were co-created with researchers, clinicians, and individuals with lived experience. The first volume is titled ***Envolvimento do paciente e do público em pesquisas*** (Longo et al., 2024), and is available at: https://repositorio.ufrn.br/items/9bd36f3e-95a9-4080-8eaa-7bea60b68a74, introduces the core concepts of PPI, its ethical foundations, and examples of international best practices. The second volume, ***Patient and public involvement in research: practical experiences from different settings*** (Longo et al., 2025), which compiles experiences from Brazil and several international partners is available at: https://repositorio.ufrn.br/items/255e1b06-26eb-4770-8a4f-95eecac08927. These e-books have been widely disseminated across Brazil, reaching graduate programs, clinical research groups, patient organizations, and government agencies. They serve as foundational materials for our training initiatives and support researchers and communities who are beginning to implement meaningful involvement practices.

There is also Family engagement in research course: each class is led by a teaching team composed of the course coordinator and three instructors, all trained in the EEP Course. The teaching teams include researchers and individuals with real-world experience. They also have the support of the Knowledge Facilitator and the Accessiblity Promotor. My role as Knowledge Facilitator is to help connect research teams with peple with lived experience and ensure everyone can work together collaboratively and feels welcomed. Accessiblity Promotor works to ensure that course materials are acccesible and provides support to participants with identified accesibility needs.

The 1st Brazilian School of Patient and Public Involvement in Research is a pioneering national initiative that took place at the end of October 2025. This first edition trained more than 30 Brazilian researchers from several states and across multiple levels of academic training—from early-career students to senior investigators. This national training initiative represents an important step in consolidating a culture of meaningful involvement in research across Brazil and aligns with international efforts toward more inclusive, equitable, and socially responsive research practices.

3. Case Study 1: Brazilian Cerebral Palsy Registry

This PPI group comprises adults with cerebral palsy and mothers of children with cerebral palsy. Too often, patients are seen as “study objects” and research projects are “about” them instead of “with” them. However, in aiming for projects that make a significant difference and have societal impact, it is essential to work together with those with lived experience. The involvement Matrix can help with involving experts by experience, or people with lived experiences. They are people whose own experiences have equipped them to become experts in a certain area. One could think about patients, but also young people with a chronic condition, their family members or elderly. Involving these experts in research project will result in new insights that project leaders might not have, while it empowers the experts by experiences. Moreover, it leads to hands-on results that can directly benefit the people focused upon in the project. Comic book was also created to facilitate involvement of the patients and public understanding that they are all protagonists and equally important.

4. Case Study 2: PartiCipa Brazil PPI Group

The *PartiCipa Brazil* PPI Group includes one adolescent with cerebral palsy and three mothers of children with cerebral palsy. This group was intentionally assembled to bring diverse perspectives on childhood participation, accessibility, and family routines. Their lived experiences provide essential insight into how participation is shaped by environmental, social and structural factors in Brazil. Our work together focuses on co-designing visual materials for the PEM-CY (Participation and Environment Measure for Children and Youth), specifically by illustrating each questionnaire item that addresses leisure and community-based activities. Many families in Brazil report difficulty understanding standardized participation questionnaires due to abstract wording, limited literacy, or unfamiliarity with research terminology. To address this gap, our group partnered with a professional designer to create culturally sensitive and easy-to-read illustrations for each PEM-CY item. These illustrations depict real Brazilian contexts—public squares, beaches, community events, church groups, sports programs, adapted leisure activities—highlighting the environments in which participation takes place. The adolescent participant and the mothers reviewed and co-constructed each drawing, ensuring that the images reflected authentic experiences rather than researcher assumptions.

University and medical students' perspective

Meaningful ethics engagement of universities for transparency and access to medicine

Toby Pepperrell*, MD, PhD student, National Committee for Universities Allied for Essential Medicines (UAEM) Netherlands, Europe

Sarai Mirjam Keestra, MD, PhD student, Epidemiology and Data Science, Amsterdam University Medical Centre, University of Amsterdam, the Netherlands 2. Universities Allied for Essential Medicines (UAEM) Europe, Berlin, Germany

* Presentation at the webinar

1. Universities' role in global research ethics

In the context of increasing demand for universities to balance between their public mission and private interests, universities must institutionalise accountability, justice, and equity in their efforts to advance global public health. As key actors in medical research and development (R&D), universities should serve the global public good by protecting participants' rights and promoting transparency, accessibility, and affordability of new health technologies. Members of the Universities Allied for Essential Medicines (UAEM) have discussed in a recent publication [15] how universities can uphold and strengthen key principles of the World Medical Association's Declaration of Helsinki (DoH), particularly those related to:

- Balancing public and private interests (Article 7)
- Protecting and prioritising vulnerable populations (Articles 6, 9, 13, 17, 19)
- Post-trial access (Article 34)
- Clinical trial transparency (Articles 35, 36)

2. Vulnerability and post-trial access

Universities and university research ethics committees should recognise their critical role in protecting research participants and ensuring that those who contribute to research benefit from its outcomes in the broadest sense, as articulated in Article 19 of the DoH. This responsibility extends beyond individual studies to include equitable benefit-sharing and inclusion of vulnerable communities in decision-making. During the COVID-19 pandemic, vulnerable populations in regions with high burdens of disease and high mortality rates faced limited and delayed access to coronavirus vaccines, despite substantial participation in clinical trials. In countries such as South Africa and Brazil, this inequity echoed similar patterns observed during the HIV pandemic. Article 34 of the DoH on post-trial access remains vague and difficult to operationalise. Universities should therefore ensure that post-trial provisions are embedded early in the research and development process, including during contract negotiations with sponsors. Research ethics committees must safeguard the public interest in these negotiations. Access arrangements should be explicit, enforceable, and long-term. Legitimate mechanisms such as open or non-exclusive licence agreements, knowledge transfer and sharing of technical know-how with generic or biosimilar manufacturers, needs-based production capac-

ity, pooled procurement, or other affordability-enhancing mechanisms should be implemented, and universities can play an important role in this process. Beyond access and benefit-sharing, transparency in research design, outcomes, and costs is equally essential to uphold public trust.

3. Clinical trial transparency

The obligation for timely and complete publication of preregistered clinical trial results in publicly accessible databases was not clearly stated in earlier versions of the DoH and remains insufficiently enforced in practice. Many clinical trials still fail to meet the legally mandated obligation to publish their results promptly, introducing bias and slowing medical progress. Transparency is a prerequisite for ensuring patient safety and public trust. Universities should adopt internal oversight systems to ensure compliance with Articles 35 and 36 of the DoH, including mandatory preregistration, timely reporting, and full disclosure of funding sources, conflicts of interest, but also lead the way in disclosing R&D costs. Transparency regarding R&D costs would clarify the contributions of public and private sectors, enabling evaluation of whether public investments result in equitable access to new technologies. Future revisions of the DoH should specify clear responsibilities, timelines, and accountability mechanisms for result publication to ensure legally enforceable transparency standards on a national and international level.

By leading efforts in these key areas (i.e. balancing public and private interests, protecting vulnerable populations and ensuring post-trial access, and advancing transparency), universities can help align biomedical research with global health equity.

製薬医学の視点

患者・市民との共創としての製薬医学

Pharmaceutical Medicine as co-creation with patients and the public

松山　琴音

国立成育医療研究センター臨床研究センター長；国際製薬医学会（IFAPP）次期会長

Kotone Matsuyama, BPharm, Director, Center for Clinical Research and Development, National Center for Child Health and Development; President-Elect, IFAPP

国際製薬医学会（IFAPP）は，各国製薬医学会と個人メンバーが25か国から参加する国際ネットワークで，現在6,000人を超えるメンバーが参加しており，その活動は月刊の機関誌で報告されています．私は2021年から倫理作業部会のチェアを担っていましたが，2025年4月から次期会長に選出されました．

日本製薬医学会（JAPhMed）がその加盟団体で，ここ数年はJAPhMed年会におけるIFAPPのアジア・セッションを私が担当しています．2024年には7月27日に「患者・市民参画のベスト・プラクティス」というテーマで，アジア地域の患者・市民参画活動を紹介するとともに，世界医師会『ヘルシンキ宣言』2024年改訂について議論しました．今日の会議にも参加している今村恭子先生，栗原千絵子先生，Ji4pe生命倫理ワーキンググループの井上恵子さんも，このセッションに参加していました．オンラインによる開催で，50名以上が参加しました．

臨床試験においては，患者，患者家族，各種専門職を含む様々なステークホルダーが意義ある参画をすることで，結果の社会的価値を最大化するという意味で，『ヘルシンキ宣言』の以下の改訂は非常に重要です．

- 「subject」という用語を「participants」に変更し，個々の参加者の権利をさらに重視する．
- 参加者には健康な対象者も含まれることを明確にした．
- 研究のあらゆる段階における参加者とそのコミュニティの参画を推進する．

では「意義ある参画」とは何でしょうか．患者に「対する」研究ではなく，患者と「ともに」行う研究，研究プロトコルやインフォームド・コンセント文書を患者とともにつくる，倫理審査委員会への一般市民の参加，患者報告アウトカム（Patient Reported Outcome：PRO，適切ならばe-PRO）の活用といったことが考えられます．これによって研究のインパクトを医療ニーズに対応したものとし，参加者の登録が促進され，結果としてリアルワールドに還元されます．そのような臨床試験の信頼，適切性，社会的価値の最大化に向けた製薬医学の展開について，IFAPPの取り組みが寄与することになればと活動しています．

Perspective of Pharmaceutical Medicine

Pharmaceutical Medicine in a New World Order: Ethical imperatives for 2025 and beyond: *First do no harm*

Varvara Baroutsou, M.D., Ph.D., Immediate Past President of IFAPP; CIOMS Executive Committee Member; Consultant in Internal Medicine and in Pharmaceutical Medicine, Athens, Greece

As the global landscape shifts under the weight of pandemics, geopolitical instability, and technological disruption, pharmaceutical medicine faces unprecedented ethical challenges. In 2025, the discipline must evolve to meet the demands of rapid innovation, equitable access, and responsible governance.

1. Defining the discipline

Pharmaceutical medicine is the medical-scientific field dedicated to the development, evaluation, and responsible use of medicines for the benefit of patients and public health. It encompasses clinical research, regulatory science, pharmacovigilance, and medical affairs—requiring a robust ethical compass to navigate its expanding scope.

2. Emerging ethical tensions

Key dilemmas include:

- Patient Safety vs. Speed to Market: Balancing commercial urgency with rigorous safety standards.
- Access and Equity: Addressing the biomedical blind spots that obscure social determinants of health.
- Global Distribution and Intellectual Property: Navigating patent protections and pricing strategies in times of crisis.
- AI and Big Data: Managing algorithmic bias, data privacy, and transparency in decision-making [16, 17]

The EU AI Act (2024/1689) introduces a risk-based framework for AI systems, with stringent obligations for high-risk applications in healthcare. This regulatory evolution demands ethical literacy across all stakeholders.

3. Building ethical culture and accountability

Pharmaceutical organisations must foster ethical education, transparent governance, and inclusive decision-making. This includes:

- Training professionals in ethical reasoning
- Strengthening clinical trial transparency
- Ensuring fair and sustainable innovation

4. Sustainability and value-based care

Environmental, Social, and Governance (ESG) principles are reshaping pharmaceutical operations from green chemistry to biodegradable packaging. Energy considerations for scaling AI adoption in medicine should “first do no harm” [18].

Therefore, it is required to assess the impact of:

- Resource demands associated with AI development and deployment
- Lifecycle considerations of data center cooling and precious mineral procurement
- Cost emission analysis and AI impact metrics for policy makers and decision
- Computational efficiency and sustainability for ensuring environmental responsibility
- Aligned policies and practices without compromising ecological longevity

Meanwhile, value-based healthcare models link drug pricing to patient outcomes, supported by real-world evidence and outcome-based contracts.

5. AI and Ethics: A converging frontier

The integration of AI into clinical care requires:

- Human-centred design
- Community-engaged development
- Privacy-preserving technologies (e.g., federated learning, differential privacy)
- Transparent and accountable governance
- Evidence based data -Data justice- Real World Data validation
- Algorithmic repair
- Policy enforcement

UNESCO's AI Ethics Recommendation and OECD principles [19] underscore the need for fairness, explainability, and protection of human rights in AI deployment.

6. Conclusion

Pharmaceutical medicine in the new world order must be guided by ethical foresight, global solidarity, and a commitment to human dignity. As AI, personalised medicine, and biomanufacturing reshape the field, ethical frameworks must evolve in tandem—ensuring that innovation serves humanity, not just markets. AI should enhance—not replace—human capabilities. It should be designed with empathy; inclusivity and it should not override ethics and human decision-making.

総括と議論への道筋

Summary of views and future initiative for consensus development

栗原千絵子
神奈川歯科大学特任教授；「臨床評価」編集長
Chieko Kurihara, BA, Specially-appointed Professor, Kanagawa Dental University;
Editor-in-Chief, *Clinical Evaluation*

今日の会議では，とても有意義な議論をできましたこと，参加者の皆様に感謝します．日本からは患者・市民がリードしてグローバル研究倫理規範に向けた『患者・市民の研究倫理宣言』が紹介されるとともに，製薬企業と患者の協働による臨床試験における患者参画の実例が紹介されました．

ブラジルからは，国の機関としての倫理審査委員会の連携組織，研究対象者の権利保護のために新たに立ち上がった組織の紹介がありました．また，1990年代から，患者やコミュニティが主導する研究のあり方が明示されてきたことや，実際にすべてのプロセスに患者コミュニティが参画する研究の実例などが紹介されました．

大学や医学生の立場で臨床試験の透明性を求めるグループからの発表，製薬医学の立場からの発表も，グローバルな研究倫理規範の刷新と患者・市民参画の重要性を強く支持するものです．

呼びかけに応じて参加してくださったフィリピン健康研究倫理評議会の患者・家族・コミュニティ参画委員会委員長からは日本の患者・市民グループの発表を高く評価していただき，WHO[20]による「意義ある参画」の定義を明記すべきとの助言もいただきました．

グローバル研究倫理と意義ある参画に向けた声明については，9月13日・15日の会議を経て，参加された皆様のご意見，賛同をいただき，国際機関に提出したいと考えていますので，どうぞよろしくお願いいたします．

グローバル研究倫理と意義ある患者・市民参画：コンセンサス形成－Part 2

主催：ブラジル生命倫理学会，医療開発基盤研究所（Ji4pe）
後援：日本医学哲学・倫理学会，国際製薬医学会，日本製薬医学会，Juju Barbosa
協力：臨床評価刊行会，生命倫理政策研究所，臨床研究リスク管理研究会
プロデュース：国立成育医療研究センター
2025年9月13日㈯ ハイブリッド（オンライン／東京）

Global Research Ethics and Meaningful Patient and Public Involvement: Consensus Development－Part 2

Organized by:
The Brazilian Society of Bioethics (SBB)
Japanese Institute for Public Engagement (Ji4pe)
Supported by:
Japanese Association for Philosophical and Ethical Researches in Medicine (JAPERM)
The Japanese Association of Pharmaceutical Medicine (JAPhMed)
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Juju Barbosa
Cooperation: Clinical Evaluation; Center for Bioethics Policy Study
Clinical Research Risk Management Study Group
Produced by:
The National Center for Child Health and Development
13 September, Saturday, 2025 (Hybrid: online / Tokyo)

301頁の*IFAPP TODAY*記事翻訳の写真キャプションを参照.
See explanation under the photo in the page 2 of the article to introduce the result of this conference in *IFAPP TODAY*. 2025; No. 58: 1-3.:
https://ifapp.org/wp-content/uploads/2025/10/IFAPP-TODAY-58-October-2025.pdf
Video:
https://www.youtube.com/watch?v=D8k3Dh6kf80

ENREC and Egyptian research governance framework: ENREC's endorsement of the GREEN Statement

Hany Sleem, MD, Head of Dermatology, National Hepatology & Tropical Medicine Research Institute; Egyptian Network of Research Ethics Committees (ENREC), Cairo, Egypt

1. ENREC and Egyptian research ethics framework

Egyptian Network of Research Ethics Committees (ENREC) was created in 2008 to raise the harmonization between Research Ethics Committees (RECs) in Egypt, operating under the auspices of NGO (Egyptian Society for Healthcare Development: ESHD). Mission is to strengthen ethical oversight of research involving humans through collaboration and capacity building. There are more than 85 registered RECs in Egypt[21].

Egyptian old Constitution in 1971 Article 43 stated that no medical or scientific experimentation may be performed on any human being without their free consent. In current 2014 Constitution Article 60 states that "..no medical or scientific experiment may be performed on any human being without their free, authenticated consent, in accordance with established principles in the field of science...". Egyptian Clinical Trial Law No. 214/2020 maintains a strong commitment to the highest ethical standards in research, with ongoing efforts dedicated to safeguarding vulnerable populations, under the supervision of the Supreme Council[21].

2. ENREC's endorsement of the GREEN Statement

ENREC endorsed the GREEN Statement soon after receiving the announcement, especially strengthening importance of:

- Dynamic consent for long-term studies;
- Accountability for post-trial benefits;
- Essential participant & community engagement;
- REC independence from sponsor influences.

Our endorsement shows Egyptian's RECs commitment to the highest global ethical standards. ENREC works directly to implement the core principles of the GREEN Statement confirming the alignment between GREEN Statement and ENREC Actions:

- Item A.1 (GREEN): Principles of Justice and protecting the vulnerable.
  →ENREC Actions: Supporting the national strategy for "categories requiring additional protection."
- Item A. 2 (GREEN): "Continuous capacity building.. ensured by an established research governance framework"
  →ENREC Actions: Training and harmonizing 85+RECs.
- Item B (GREEN): "Meaningful engagement" and community partnership.
  →ENREC Actions: Ensuring RECs include civil society and engaging with local communities.

We immediately prepared Arabic translation of GREEN Statement, to ensure concepts like "vulnerability" resonate culturally and legally. The process of empowerment enables true participation in the global ethics discourse from the region. This is a practical implementation of the WHO's principles of "Meaningful Engagement".

3. The Ethical Imperative: beyond the trial to affordable access

Conducting trials in developing countries is only one part of the research lifecycle. It is fundamentally unfair to use participants from communities with limited resources to develop medicines that remain financially out of their reach. The pain of knowing a life-saving treatment exists but is unaffordable can be more devastating than having no treatment at all. This creates massive psychological and financial distress for patients and families.

4. Bridging the gap: from ethical principle to practical solution

Core research ethics issues are:

- The principle of justice requires the equitable distribution of the benefits and burdens of research;
- Communities that bear the risk of participation must share in the benefits of the resulting knowledge;
- Aligns with Global Norms;
- Declaration of Helsinki 2024 strengthens accountability for post-trial access and benefit sharing;
- GREEN Statement (Item A.2) mandats that benefits should be shared among study participants, the community and globally to achieve equity.

5. Integrating access into ethics

Ethical review must include access plans.

Considerations needed for sponsors and researchers:

- Proactive planning: submit affordable access strategies for post-trial market entry as part of their ethics application;
- Transparency: disclose R&D costs and justify pricing models to regulatory authority;

Considerations needed for RECs;

- Inspect access: make the assessment of post-trial access and affordability plans a mandatory part of the ethical review process;
- Advocate for participants: uphold the principle of justice by demanding that the benefits of research are accessible to the community that made it possible.

ENREC's commitment:

- ENREC will defend the right to affordable access as a fundamental component of ethical research;

Our strategy:

- Capacity building: Train REC members across Egypt to critically evaluate access and future pricing plans;
- Policy advocacy: work with national regulation to strengthen guidelines that mandate affordable access as an ethical requirement;
- Global voice: advocate within international forum for equity in the development and pricing of medicines.

True ethical research does not end at proving efficacy; it only succeeds with it delivers hope that is accessible.

「グローバル研究倫理規範と意義ある参画：GREEN声明」に向けた議論

Discussions toward consensus development for GREEN Statement

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[English version is from page 265.]

1. イントロダクション：本会議の目的と構成

冒頭でGREEN 声明オーガナイザーが，8月25日の会議以前に用意され，9月13日の会議の前に略称を定めた『GREEN 声明』の趣旨と本日のハイブリッド会議進行について説明した．本声明のフル・タイトルは「グローバル研究倫理規範と意義ある参画に向けた声明：Global REsearch Ethics Norm and Meaningful Engagement」であり[13]，英文の頭文字をとったアクロニム（頭字語）による略称を『GREEN

声明』とした．この声明は，世界医師会『ヘルシンキ宣言』2024年10月改訂に際して，その改訂版採択の直前に国際的ネットワーク（後にGREEN声明オーガナイザーとなるメンバーの発案）により出版された『ヘルシンキ声明』[11]，及びJi4pe生命倫理ワーキンググループが出版した『患者・市民の研究倫理宣言』[3]に基づき，オーガナイザーらが寄稿して2025年9月17日にSpringer社より出版された書籍『ヘルシンキ宣言2024年改訂：最高の倫理水準に向けたグローバルな努力（*The 2024 Declaration of Helsinki: Global Efforts Towards the Highest Ethical Standard*）』[22]及びこれより前に出版された同じ編者・多くの同じ著者による書籍『グローバルヘルスのための倫理的イノベーション：パンデミック，民主主義，研究倫理（*Ethical Innovation for Global Health: Pandemic, Democracy and Ethics in Research*）』[23]における議論その他のグローバルなネットワークとの議論を踏まえて準備された．そして本日の外国人講師2名を招いてのハイブリッド会議，9月15日の日本医学哲学・倫理学会での国際シンポジウムでの議論を経て，国際連合（UNESCO, WHO），国際医学団体協議会（CIOMS），世界医師会（WMA）に向けて提出されるものとして計画された．

本会議では，エジプト倫理委員会ネットワークより本声明への賛同を示す発表に続いて，GREEN声明のItem A, Bを各項目に特に関連した講師・参加者により読み上げ，議論した．

これにより，9月15日の国際会議を経てグローバルに発信すべき『GREEN声明』についての合意形成をはかることが本会議の目的である．

2. ENREC発表後の議論

招聘講師・患者代表のコメンテイターからは以下のようなコメントと質疑があった．

Baroutsou　ENRECが患者の権利保護を確保し，コミュニティの能力をエンパワーするためにネットワークを形成していることは大変に素晴らしい．こうした活動が包摂性を高めることが研究の社会的価値を高めることになると考えます．

Greco　ENRECのアクセスに向けた取り組みは極めて重要です．ブラジルではCONEP（Brazilian National Commission on Ethics in Research）という法的規範に基づく国の機関が全国にあるResearch Ethics Committeesをとりまとめており，バイオバンクは89件が登録されています．ブラジルでは2024年の5月，“Brasil Instituto Nacional de Participantes de Pesquisa Juju Barbosa”（National Institute of Research Participants Juju Barbosa）という組織がつくられました．研究参加者の「解放」（emancipation）により自らの権利を明らかにすることを目的としています．

奥瀬　日本では研究倫理が一般市民・社会にとってなじみ深いものではなく，このため患者たちにとっても研究参加がなじみにくいものとなっています．ENRECではどのように取り組んでいるのでしょうか．

Sleem　ENRECのようなネットワークにはグループとして患者・市民参画を推進するpriorityがあり，SNSを使ってアウトリーチする方法も有効です．Community membersをinvolveすることで研究結果から得られるベネフィットを社会に還元することができます．

3. GREEN声明についての合意形成のための議論

続いて，GREEN声明を一行ずつ読んで，合意形成に向けた議論が行われた．以下は議論の要約である．

●Item A「グローバル研究倫理規範」のための項目

- 世界医師会『ヘルシンキ宣言』は1964年に初版が採択され，2024年に10回目の改訂が採択されたが，GREEN声明オーガナイザーは『ヘルシンキ声明』[11]発出においてもオーガナイザーとして貢献し，そのうち4名（VB, DG, CK, KM）はヘルシンキで開催されたWMA総会に参加した．『ヘルシンキ声明』では10項目の改善点を評価し，その中には研究参加者・コミュニティの参画の推進，研究に

おける不公平に対する認識，脆弱性についての考え方の変化，データ駆動型研究に対応した台北宣言の取り入れなどが含まれる．

- Subjectがparticipantに変更されたことも大きな変化だが，アラビア語，ギリシャ語，ブラジルにおけるポルトガル語ではDoHの2024年改訂以前からparticipantの意味の用語をあてていた．このことは，研究対象者を単なる観察対象である物体のようにみなす考え方とは異なる考え方を示している．
- ヒポクラテスのfirst do no harmに基づきリスクから人を守ることが重要だが，研究によるベネフィットを社会に還元するためにも，患者・市民のアクティブな参画が必要である．
- 『ヘルシンキ声明』の後半ではプラセボ対照試験，試験終了後アクセス，社会的価値，研究の透明性，平易な言葉による規範，の5項目を残された課題として挙げた．ヨーロッパでは確立した介入がある場合にはプラセボ対照試験は行えなくなっている．ブラジルでは国の規範としてそれを許容せず，ラテンアメリカ諸国でも機関・組織が同様の方針を採用している．米国では確立した介入がある場合にプラセボや効果が低い介入を対照にすることを許容しており，それは配分的正義の観点からフェアではなく，効果が十分ではない医薬品が承認されることは，限られた保険財政の無駄遣いであり患者が最善のものにアクセスする機会を奪う．
- エジプトでは，プラセボ対照試験，また健康な対象者を対照群に置く研究で子どもを対象とするものもあり，そうした試験には正当性評価が必要である．
- 『ヘルシンキ宣言』は医師のみによって最終決定されるが，UNESCOの生命倫理・人権宣言は今年20周年を迎えたが，195か国が参加して採択したものであり，CIOMS指針は医師に限定されない委員によりWHOと協働で作成されたものである．
- 研究のゴールはSDGsに向かうべきであり，環境や社会，未来世代への影響をnegativeな影響も含めて評価すべきである．
- 証明された介入へのアクセスを確保するための道筋の一つとして，TRIPS Agreementに対する

Doha宣言（知的財産権の保護よりも公衆衛生を優先する），COVID-19の期間中に南アフリカとインドが提案したTRIPS Waiverなど，知的財産権のマネジメント戦略を関連するコミュニティが保持することが重要である．

- 研究によって証明された介入をaffordableなものとしなければならない．そのためにも“equality”の語は“equity”であるべき．さらに，研究データの再現性（reproducibility）が確保されることが重要である．

●Item B「意義ある参画」の項目

- 8月25日の会議でフィリピン健康研究倫理評議会（Philippine Health Research Ethics Board）の患者・家族・コミュニティ参画委員会（Committee on Patient, Family and Community Engagement）の委員長よりWHO[20]による「意義ある参画」の定義，原則を明記すべきこと，フィリピンで作成した研究参加者の権利章典（Bill of rights）についてのinfographicsの提供があり，これを取り入れることにした．
- リサーチガバナンスの要素として意義ある参画が組み込まれなければならない．ギリシャでは質問をする慣習があり，市民が教育を受ける機会がある．ヘルスリテラシーの教育，継続的な教育が重要であり，ヒポクラテスの誓いは教育のベース医師にとってスタートである．
- 一方で，教育を充分に受けていない人も参画できる必要がある．
- すべての教育プロセスは人権に基づくものでなければならない．知る権利（right to know），“Nothing about us without us”などの理念，Freireの『被抑圧者の教育学』（Pedagogy of the Oppressed ）Oppressedの方法論によるべき．

『患者・市民の研究倫理宣言』は，共同作業者である南アフリカのProf. Ames Dhai（Steve Biko Center for Bioethicsの創設者，文献22, 23の共同編者）のアドバイスによって作成された．アパルトヘイト撤廃に寄与し拘留中に殺害されたSteve Bikoが南アフリカの生命倫理の原点であること，現在も世界中で非人道的な戦争・紛争が続いていることを思い起こし，研究倫理を考えるときにあらゆる非人道的行為を決して繰り返さないという決意が必要である．

［English version, same contents as the Japanese version from page 262.］

1. Introduction: objective and construction of this meeting

At the opening of the meeting, the GREEN Statement Organisers explained the purpose of the Statement. It was prepared prior to the 25 August meeting and before the 13 September meeting its acronym “GREEN” was defined. The full title of this Statement is “Global REsearch Ethics Norm and Meaningful Engagement”[13]. This Statement was discussed and being agreed by an international network, based on the “Helsinki Statement”[11] and the “Patient Public Declaration of Research Ethics”[3] issued in response to the World Medical Association’s 2024 revision of the DoH adopted in October 2024, also resulting from the discussions in the book “*The 2024 Declaration of Helsinki: Global Efforts Towards the Highest Ethical Standard*”[22], following another book “*Ethical Innovation for Global Health: Pandemic, Democracy and Ethics in Research*” published earlier[23]. The GREEN Statement was planned for submission to the international organisations engaged in international research ethics norms: the United Nations (UNESCO, WHO), the Council for International Organizations of Medical Sciences (CIOMS), and the World Medical Association (WMA).

During this session, following a presentation from the Egyptian Network of Research Ethics Committees expressing their endorsement of the GREEN Statement, items A and B of the Statement were read aloud by participants.

2. Discission following the ENREC's presentation

Baroutsou　It is truly commendable that ENREC is creating a network to ensure the protection of patients' rights and empower community capacity. I believe such activities, by enhancing inclusivity, will elevate the societal value of research.

Greco　ENREC's efforts towards access are of paramount importance. In Brazil, CONEP (Brazilian National Commission on Ethics in Research), a national body based on legal norms, coordinates Research Ethics Committees nationwide, with 89 biobanks registered. In May of 2024, 'Brasil Instituto Nacional de Participantes de Pesquisa Juju Barbosa' (National Institute of Research Participants Juju Barbosa) was established. This is an organisation for emancipation of research participants clarifying their rights.

Okuse　In Japan, research ethics is not a familiar concept for the general public or society. This makes also less familiar for research participants. How is ENREC addressing this?

Sleem　Networks like ENREC have a priority to promote patient and public involvement as a group. Using social media for outreach is also effective. Involving community members enables the benefits derived from research findings to be returned to society.

3. Discussion for Consensus-Building on the GREEN Statement

Next, the GREEN Statement was read line by line to facilitate consensus-building. The following is a summary of the discussion.

●Item A for the "Global Research Ethics Norm"

- The DoH was first adopted in 1964, with its tenth revision adopted in 2024. The GREEN Statement organisers also contributed as organisers to issue the "Helsinki Statement"[11], with four of them (VB, DG, CK, KM) participating in the WMA General Assembly held in Helsinki. The Helsinki Statement clarified 10 points of improvement in the 2024 DoH, including promoting the engagement of research participants and communities, recognising structural inequities in research, shifting perspectives of vulnerability, and incorporating the Taipei Declaration to address data-driven research.
- The change from "subject" to "participant" represents a significant shift. However, Arabic, Greek, and Brazilian Portuguese had already used a term meaning "participant" prior to the 2024 DoH. This demonstrates a different perspective from viewing "research subjects" merely as objects to be observed.
- While protecting people from risk remains paramount, grounded in Hippocrates' oath of "first do no harm", the active participation of patients and the public is also essential to ensure research benefits to be returned to society.
- The latter part of the Helsinki Statement identified five remaining challenges: placebo-controlled trials, post-trial access, social value, research transparency, and norms described in plain language. In Europe, placebo-controlled trials are no longer permitted when an established intervention exists. Brazil does not permit them based of legally-binding resolutions. Latin American institutions and organisations also adopted almost the same policy. The United States permits the use for control group

of placebos or interventions with low efficacy when established interventions exist. This is unfair from the perspective of distributive justice. The approval of medicines with insufficient efficacy represents a waste of limited public health budget and deprives patients of access to the best proven interventions.

- In Egypt, RECs sometimes have to assess placebo-controlled trials and some studies with control group with healthy volunteers, even with healthy children. Such studies need justification.
- The DoH is finally determined by physicians alone. Meanwhile, the 2005 UNESCO Declaration on Bioethics and Human Rights, which marks its 20th anniversary this year, was adopted with the participation of 195 countries. The CIOMS guidelines were developed in collaboration with the WHO by a working group members not limited to physicians.
- The goals of research should align with the SDGs, and impacts on the environment, society, and future generations should be assessed, including negative impacts.
- It is crucial that relevant communities retain intellectual property management strategies. Good examples are shown in, e.g., the TRIPS Doha Declaration (to prioritise public health over intellectual property protection) and the TRIPS Waiver proposed by South Africa and India during the COVID-19 pandemic, as pathways to ensure access to proven interventions.
- Proven interventions must be made affordable. To this end, the term "equality" should be replaced with "equity". Furthermore, ensuring the reproducibility of research data is vital.

●Item B for "Meaningful Engagement"

- At the 25 August meeting, the Chair of the Committee on Patient, Family and Community Engagement of the Philippine Health Research Ethics Board introduced the definition and principles of "meaningful engagement" by the WHO [20], along with infographics concerning the Bill of Rights for research participants developed in the Philippines. These are incorporated in the GREEN Statement.
- Meaningful Engagement must be incorporated as an element of research governance. In Greece, there is a tradition of questioning, and people have opportunities for education. Health literacy education and continuous education are crucial; the Hippocratic Oath forms the educational foundation for physicians.
- It would be also important for those who have not received sufficient education to be able to participate.
- All educational processes must be grounded in human rights, based on principles of the Right to know, and the principle of "Nothing about us without us". Freire's methodology from his work Pedagogy of the Oppressed would be also crucial.
- Patient Public Declaration of Research Ethics was developed with the advice of our collaborator, Prof. Ames Dhai of South Africa (founder of the Steve Biko Centre for Bioethics and co-editor of references 22, 23. Recalling Steve Biko, who contributed to the abolition of apartheid and was killed while in detention, is the origin of bioethics in South Africa, and that inhumane wars and conflicts continue worldwide today, it is essential to resolve never to repeat any inhumane behaviors when considering research ethics.

グローバル研究倫理の変革：ヘルシンキ宣言2024年改訂における患者・市民参画と脆弱性に関するダイナミックな考察

主催：日本医学哲学・倫理学会 第２回国際大会
セッション・プロデュース：国立成育医療研究センター
2025年9月15日（月）神奈川大学みなとみらいキャンパス

Transformation of the global research ethics: the 2024 revision of the Declaration of Helsinki to promote patient engagement and dynamic consideration on vulnerability

Organized by:
The Japanese Association for Philosophical and Ethical Researches in Medicine (JAPERM) Second International Conference 2025, Open Symposium
Session Produced by:
The National Center for Child Health and Development
15 September, Monday, 2025, at Kanagawa University, Minato Mirai Campus, Yokohama, Japan

301頁の*IFAPP TODAY*記事翻訳の写真キャプションを参照.
See explanation under the photo in the page 3 of the article to introduce the result of this conference in *IFAPP TODAY*. 2025; No. 58: 1-3.:
https://ifapp.org/wp-content/uploads/2025/10/IFAPP-TODAY-58-October-2025.pdf

趣旨説明
Introductory Remarks

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Editor-in-Chief, *Clinical Evaluation*

本シンポジウムの発表者たちは世界医師会（WMA）『ヘルシンキ宣言』（DoH）2024年改訂に対し10項目の改善点と5項目の問題点を示す『ヘルシンキ声明』[11]を世界に発信しました．問題点のうち特に重要なのはプラセボ対照試験と試験終了後アクセスですが，この点についてWMA総会の医療倫理委員会でウルグアイ医師会が動議を出しました．『ヘルシンキ声明』はこの動議を支持するもので，主としてグローバルサウスとアジア，地中海地域の24か国の125人の賛同を得ました[24]．

「意義ある参画」を推進するためには，参加者を保護するとともに研究成果を研究参加者，研究実施コミュニティ，そして世界中で必要とする人々へと還元するために強化されたグローバル研究倫理規範が必要です．

そして，弱者の研究参加を推進するためには，アドボカシーが必要であり，「私たち抜きに私たちのことを決めないで」というメッセージを重視し，研究倫理の発展における搾取の歴史を省察する必要があります．

『グローバル研究倫理規範と意義ある参画』は，このような状況を考慮し，患者・市民を含むすべての関係者が平等に意見表明する機会を得て作成すべきものです．『ヘルシンキ声明』はその出発点であり，『患者・市民の研究倫理宣言』を基盤とします．

このため本日のシンポジウムに先立ち，8月25日にはオンライン会議を，9月13日には対面とオンラインのハイブリッド会議を開催しました[25～29]．ブラジルからは，憲法に基づく倫理審査機関と研究参加者が協働する活動が開始されています．多くの方々からご意見と賛同をいただき，国連（UNESCO, WHO），CIOMS，WMAに届けることを計画しています．

研究参加者の基本的権利
Fundamental Rights of Human Research Participants

齊尾　武郎
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Takeo Saio, MD, Department of Internal Medicine and Psychiatry, Fuji Toranomon Orthopedic Hospital; Associate Member of the World Medical Association

私は3つの領域（総合内科，精神科，労働衛生）の業務に従事する医師であり，根拠に基づく医療（EMB）運動の日本での初期の主唱者の一人です．

医学の歴史においては，第二次世界大戦中のナチス医師や日本帝国陸軍の731部隊などによる非人道的な人体実験がありました．第二次世界大戦後も，開発途上国でのプラセボ対照試験，CIOMS報告書[30]に示される“ethics damping”など，人権侵害は続いています．研究参加者の人権の基盤となる規範はGREEN声明[13]のA.1に示されるようなもので，人間の尊厳，基本的人権と平等，自律性，無危害，正義の原則などです．研究に特有のものとしては，人間は他の目的のための単なる手段としてはならない（カントの格率），同意なしの人体実験の禁止（国際人権規約，ニュルンベルク綱領），研究参加者の権利と利益は研究の目的に優先する（DoH）[10]，などです．

こうした規範はよく知られていますが，法的拘束力のある包括的なグローバル研究倫理規範となる国際条約は存在しません．そのような規範は患者・市民のイニシアチブにより作成すべきです．DoHは医師によって作成されたものであり，ジュネーブ宣言に基づき患者の権利を最優先することを言明しながら，プラセボ対照試験に関する条文はその中核的原則と矛盾しており，DoHの根本精神を犠牲にしています．この状況を改善するため，GREEN声明が示す患者・市民主導の研究倫理規範が国際規範として採択されることを期待します．

『GREEN声明』に向けた患者・市民の思い

Thoughts of patients and public on issuing the “GREEN statement”

齊藤　嘉子

乳がんサバイバー；医療開発基盤研究所（Ji4pe）生命倫理ワーキンググループ

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私は乳がんサバイバーとしてピアサポート活動に従事しています．本年から倫理審査委員会に一般委員として参加することになりました．ワーキンググループのメンバーとともに患者の権利を守るためのバイオエシックスを学び，研究に積極的に参画したいと考えています．

近年，既存の医療の限界を超えるための先端医療技術として，ゲノム編集，脳オルガノイド，多能性幹細胞などの技術開発が進められています．そうした技術が治療法のない疾患に恩恵をもたらすことが期待されるとともに倫理的な懸念を喚起しています．このため，研究開発の早い段階から患者・市民が参画する必要があります．

日本では，内閣府でiPS細胞から卵子をつくることを条件付き承認する意見をまとめました．この技術は不妊治療の研究に寄与するかもしれませんが，倫理的には深刻な問題があります．

2024年10月，私たちは『患者・市民の研究倫理宣言』[3]を発表しました．それは医師が中心となって作成された『ヘルシンキ宣言』2024年版[10]にはない考え方を示しています．研究開発においては環境，社会，未来世代への影響も考える必要があります．差別や偏見を避けるための取り組みも必要です．私たちは国連の持続可能な開発目標（SDGs）を支持します．

『患者・市民の研究倫理宣言』はグローバル研究倫理規範の基盤となっています．GREEN声明が国連（UNESCO，WHO），CIOMS，世界医師会などの国際機関に届けられ，取り入れられることを願っています．

患者・市民との共創としての製薬医学：GREEN声明の意義

Pharmaceutical Medicine as co-creation with patients and the public: for the achievement of the gool of GREEN Statement

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1. 製薬医学と患者・市民参画

私は2005年4月から国際製薬医学会（IFAPP）の次期会長（President-elect）として活動しています．それ以前は2021年より倫理作業部会のチェアとして，世界医師会『ヘルシンキ宣言』[10]改訂に関わってきました．本日のテーマと関連してベネフィット共有[31]，弱者の概念の変化を踏まえたコミュニティ参画と試験終了後アクセス[32]などについても論文を発表してきています．

IFAPPは製薬医学を専門とする学術団体として，臨床試験における患者，患者家族，各種専門職の学際的な参画についても議論を重ねてきています[33, 34]．『ヘルシンキ宣言』2024年改訂を踏まえて，研究のあらゆる段階における参加者とそのコミュニティの参画を推進するにあたり，様々な方法論を検討していく必要があります．

研究プロトコルやインフォームド・コンセント文書の作成，それらを評価する倫理審査委員会に，患者，コミュニティ・メンバーが参画することが極めて重要です．特に，「患者報告アウトカム」（Patient Reported Outcome：PRO，適切ならばe-PRO），「患者経験データ」（Patient Experience Data：PED）については，科学的妥当性を確保しながら，社会的価値のあるデータを生み出す方法論を構築していく必要があり，そうした活動に取り組んでいます．

2. 先端医療技術の研究開発と患者・市民参画

IFAPPの倫理作業部会の活動では先端医療技術の活用における倫理的問題についても課題として取り組んできました．2024年のDoH改訂を踏まえて検討すべきことは，アンメット・ニーズに対応した課題を同定し，臨床試験の実現可能性を検討し，ステークホルダーが求めるコミュニケーションを重ねることで，標的となる技術のリスクとベネフィット，社会的価値を対象者集団に対して明確に説明できることが重要です．こうした技術の対象となりうる脆弱な状態にある人々に十分配慮して，患者個人・地域コミュニティの人々にとってのリスクとベネフィット評価を継続的な対話によって共有し，結果を地域での実装に結びつけることができるように協働する必要があります．予測が難しい有害事象の発生に備え，研究参加者がどのように保護されるのか，十分に説明する必要があります．

試験終了後アクセスについては，研究プロトコルやインフォームド・コンセント文書の中で明示的に言明すべきです．そのために製造スケジュールを確保し，承認申請・承認取得後の製造販売に向けた道筋を開発の早期の段階からコミュニティと協働することによって明確にする必要があります．企業，アカデミア，規制当局の協働は，患者・研究参加者・地域コミュニティの参画を得て，社会共創による価値の最大化に向けることになります．

先端的な医療技術の中でも人工知能（artificial intelligence）の研究開発においては，臨床試験登録，個別参加者データ共有，個人データの二次利用，プライバシー保護についての検討が必要となり，世界医師

会の『台北宣言』がDoHで引用されたことが大きな意味を持ちます.

GREEN声明は，こうした製薬医学の新たな課題に対応して，患者・市民グループからの発案を取り入れ，協働として進めていくことに意義があります.

Building Consensus on a Statement on Global Research Ethics and Meaningful Patient and Public Involvement

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1. Establishment of participatory principles

"Participatory Research" and "Stakeholder Engagement" are well established ideas in existing documents [4, 5, 8, 9]. We must clarify what is owed to participants after a clinical trial. The 2002 CIOMS Guidelines [35] emphasized ethical principles in research in resource-limited settings (Guideline10) and the ethical obligation of external sponsors to provide health-care services (Guideline 21). Both principles have been expanded and deepened in the current 2016 CIOMS version [8].

2. Establishment of benefit sharing and post-trial access

In addition, benefit sharing and post-trial access have been supported by the 2005 UNESCO Universal Declaration on Bioethics and Human Rights [7] - Article 15: Sharing of benefits, by the. 2007 UNAIDS/WHO guidance document Ethical considerations in biomedical HIV prevention trials Guidance [36] Points 12–Benefits & 14-Care and Treatment and by the 2010 WHO Guidance on ethics of tuberculosis prevention, care and control [37]- Free access to drugs; guidance for research. The 2000 version of the World Medical Association's Declaration of Helsinki established the guarantee of post-trial access. However, this was downgraded in the following versions.

3. Brazilian decision to the right of post-trial access

This Brazilian position was clarified in 2012 Brazilian Research Ethics Commission, Resolution 466: Post-trial access. This was an important decision, but discussions about the right to post-trial access are "old", as access to an established safe and effective intervention must be guaranteed to everyone in the context of public health and not limited to participants in a clinical trial.

4. 2024 WMA Declaration of Helsinki and Helsinki Statement

There were significant modifications to the 2024 DoH [10]. We issued "Helsinki Statement" [11] listing 10 positive points, while expressing our concern that important items were rejected. As the DoH has long been a driving force and respected document for ethics in human research, WMA should aim for the ideal of the highest ethical standards being applied. It is worth emphasizing that the 2000 DoH presented the highest protection to research participants in terms of placebo use and post-trial access. The 2000 DoH defined that:

- **Placebo-controlled trials must be permitted only when there is no proven intervention.**
- **Post-trial access must be ensured to study participants who still need the intervention.**

We very much hope that these two ethical principles will be agreed by relevant stakeholders, their institu-

tions or organizations and jurisdictions, and implemented in research and research review settings, and consequently be incorporated in future revisions of the DoH. The proposals of the Helsinki Statement aim to maximize the ethical impact of the DoH on research practice, research review process and in the protection of participants worldwide. Furthermore, the principles of research ethics must be strengthened with the equal participation of all relevant stakeholders, including civil society, not limited to physicians.

5. Responsibility of Research Ethics Committee

It is important to highlight that, according to the DoH, the responsibility for examining the justification of "exceptional cases" of "post-trial provision" lies with Research Ethics Committees (REC). What are the justifiable exceptional cases? Will the RECs have the power to make these decisions?

6. Next Step (1): emancipation of patients and the public

To this end, a Japanese patient public group, Ji4pe, issued The Patient Public Declaration of Research Ethics [3] stating: "*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*". In Brazil, Instituto Nacional de Participantes de Pesquisa Juju Barbosa (The Juju Barbosa National Institute of Research Participants) was created with the goals of contributing to the emancipation of research participants and the unequivocal defense of their rights, as well as the inclusion of the social value of research [12]. This emancipation will occur though the exercise of protagonism and the relevance of social control, in research spaces, in accordance with the norms of the Brazillian CEP/CONEP System.

7. Next Step (2): The Statement for Global Research Ethics Norm and Meaningful Engagement: GREEN Statement

Through the aforementioned activities, we proposed the Statement for Global Research Ethics Norm and Meaningful Engagement: GREEN Statement [13]. (The full text of the Statement is published in this issue of the Journal *Clinical Evaluation*.)

Based on Paulo Freire's idea of emancipation [6], meaningful patient/participant involvement must be used as a stepping stone toward the more elusive goal of achieving adequate access to public health for all.

Therefore, we must reiterate that the status quo of inequality, violence, genocide, homophobia and xenophobia is not immutable and that in these turbulent times we need a norm that must serve as a compass to guarantee the right of all people to live with dignity, safety, and health. Establishing a Global Research Ethics and Meaningful Patient and Public Engagement Norm is a step in this direction.

"Nothing about us, without us" is a well-known message during the process of establishment of United Nations Convention on the Rights of Persons with Disabilities (CRPD) adopted on December 13, 2006.

In conclusion, a historical reflection: Thucydites wrote in his book "The Peloponnesian War" that Justice will only come when those who are not victims of injustice are as indignant as those who are. This suggests the idea of "empowerment".

I would argue that Justice will prevail when those affected and indignant by injustice can fight for their rights. This represents a shift towards the idea of "emancipation".

Reimagining Ethics in Pharmaceutical Medicine: A Global Call to Action: The GREEN Statement

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In an era marked by rapid technological advancement and global health challenges, the ethical foundations of pharmaceutical medicine demand renewed scrutiny. The evolving "Statement on the Ethics of Pharmaceutical Medicine in the New World Order"—developed collaboratively by an independent group of international experts—offers a forward-looking framework to guide research and innovation with integrity, inclusivity, and sustainability.

Anchoring Ethics in Global Norms

The GREEN Statement [13] draws upon foundational principles from Hippocratic Oath, Kantian ethics, the International Covenant on Civil and Political Rights (Article 7) [38], and the Declaration of Helsinki. It reaffirms the primacy of participant rights, autonomy, and justice, while integrating perspectives from the Belmont Report [39, 40] and Beauchamp & Childress's bioethical framework.

Expanding the Ethical Horizon

Key areas for enhancement include:

- **Digital and Data Ethics**: Beyond AI, the Statement calls for attention to data sovereignty, algorithmic bias, and cybersecurity.
- **Emergency Research Ethics**: Ethical rigour in crisis contexts—pandemics, disasters—must balance urgency with protection of vulnerable populations.
- **Youth and Marginalised Voices**: Greater inclusion of indigenous communities, persons with disabilities, and intergenerational ethics is essential.
- **Funding Transparency**: Proposals include independent oversight and disclosure standards to mitigate conflicts of interest.

From Principles to Practice

Operationalising "meaningful engagement" with patients and the public is central [8, 41]. Drawing on WHO guidance [20], the Statement advocates for measurable indicators, inclusive language, and shared decision-making. It also may serve :

- **A Global Ethics Observatory** to monitor breaches and share best practices.
- **Ethics Education** for all stakeholders, including modules on cultural humility and digital ethics.
- **Ethics Impact Assessments** for major research initiatives.

Green Statement of Ethics: Bridging Health and Sustainability

The GREEN Statement introduces a pioneering "Green Ethics" agenda, exploring:

- Eco-conscious clinical decision-making
- Green informed consent
- Sustainable research practices [42)]
- Environmental justice in global health
- Ethical stewardship of pharmaceutical waste

Frameworks such as RE4GREEN [43)] are highlighted as vehicles for embedding environmental integrity into biomedical innovation.

Towards a Shared Future

This evolving GREEN Statement invites global dialogue and endorsement. It seeks to harmonise ethical standards while respecting local contexts, fostering solidarity, and ensuring equitable benefit-sharing. As the finalisation process continues, stakeholders are encouraged to contribute via the public consultation link: https://forms.gle/EfhDgMb3JeFNLaMY7

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