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

The Statement for Global REsearch Ethics Norm and Meaningful Engagement GREEN Statement

著者：GREEN Statement Initiative
（著者となることに同意した方を含む賛同者の名前は末尾を参照）
（本文2025年9月17日，賛同者10月31日まで）

この声明の目的は，研究参加者とそのコミュニティの権利を守り研究の社会的価値を生むため，国際的な研究倫理文書を作成する国際団体に対して『グローバル研究倫理規範と意義ある参画に向けた声明』を取り入れるよう求めることです．このため，オンラインと対面による３回の連続会議とe-mailの議論を経て，この声明は国際連合（UNESCO，WHO），国際医学団体協議会（CIOMS），世界医師会（WMA）*に届けられています．

この声明に対する意見・賛同を歓迎します．2025年10月末までの共著者及び／又は賛同者（19か国より91名，うち複数名をカバーする17の組織としての賛同）の氏名（適切ならば所属）は，「臨床評価」誌53巻２号**に掲載されます．出版前の最終版は賛同者に共有され，その時点での辞退（オプトアウト）も可能としました．

この声明は，独立のオーガナイザーにより組織され，ブラジル生命倫理学会と医療開発基盤研究所（Ji4pe）主催によりグローバルな参加者とともに８月25日と９月13日の２回のオンライン及びハイブリッド会議で議論され，最終的に９月15日の日本医学哲学・倫理学会の第２回国際大会（横浜）で検討され，９月17日に最終ドラフトが上記国際機関の一部に届けられました．これらの会議のProceedingsは上述の「臨床評価」誌の同じ号**に掲載されています．賛同・意見は声明に対する今後の議論のため下記リンクから暫くの間，登録することができます．

（オリジナル英語版からの和訳：栗原千絵子）

https://forms.gle/EfhDgMb3JeFNLaMY7

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＊UNESCO= United Nations Educational, Scientific and Cultural Organization; WHO=World Health Organization; CIOMS= Council for International Organizations of Medical Sciences; WMA=World Medical Association.

＊＊「臨床評価」53巻２号（和文）：https://cont.o.oo7.jp/53_2/53_2contents.html
同（英文）：https://cont.o.oo7.jp/53_2/53_2contents_e.html

私たちは，人間が参加する研究が参加者の権利と福利を守りグローバルな健康問題を解決する価値を生むための最高の研究倫理基準の作成に向けて努力するグローバルなネットワークです．この目的のため，私たちはすべての関心ある人々が研究のあらゆる段階に生産的で意義ある参画をすることを奨励します．この目的を共有し互いを尊重し協力する方は誰でも，ネットワークへの参加

を歓迎します．この声明の目的は，国際機関に私たちが提案する「グローバル研究倫理規範と意義ある参画」を取り入れるよう求めることです．

世界医師会の『ヘルシンキ宣言』[1]は，人間を対象とする研究の倫理原則として最もよく知られるものの一つであり，1964年に採択され2024年に10回目の改訂が行われました．最新改訂では，研究参加者とそのコミュニティが研究の計画，実施，結果の普及などあらゆる段階で参画することを推奨しています．また宣言は研究における不平等を警告しつつ，脆弱な参加者が十分に保護され，研究から得られるベネフィットを受けられることを確保しつつその研究参加を推進する道筋を明確化しました．さらに，人工知能（AI）の研究開発に大量の個人データが使われる状況に鑑み，研究で得られるデータや人体由来試料の二次利用においてはヘルスデータベースとバイオバンクに関する『台北宣言』[2]に従うよう推奨しています．

『ヘルシンキ声明』[3]は，上述の点を含み2024年改訂の重要ポイントを支持しつつ，残された課題についての異議を明示し，2024年10月18日に発表されました．これに対して2024年11月までに，24か国からの125人より賛同を得ました[4]．

https://cont.o.oo7.jp/52_3/p483-98.pdf

さらに2024年10月10日には，日本の患者・市民が主導して『患者・市民の研究倫理宣言』[5]が発表されました．それはあらゆる関心ある人々の平等な参画により，持続可能な開発目標（SDGs）[6]の観点からグローバルな社会課題に立ち向かい，未来世代や生態系への影響も含めて精神的・社会的インパクトを考慮する研究倫理規範の作成を推奨するものです．

https://cont.o.oo7.jp/52_3/p463-74.pdf

こうしたイニシアチブに対応して，国際研究倫理文書[1, 7～10]を作成する機関においては，将来に向けて下記の項目（Items A）を取り入れることを強く推奨します．

さらに，『ヘルシンキ宣言』その他の国際的な倫理に関する文書[10～13]に記載される「意義ある」参画が実現されるよう，下記の要素（Items B）が実効性あるものとなるようにそれぞれの分野で国際的協力を進めるよう努力します．このような目的のため，私たちは「意義ある」患者・市民参画のために必要な要素についての声明へのコンセンサス形成を始めます．

グローバル研究倫理規範（Items A）と意義ある参画（Items B）に含まれるべき項目

Items A：グローバル研究倫理規範[14]

1．研究倫理の基盤として参照される基本的な規範

- 何よりも，害してはならない（Hippocrates[15]）．
- 人間は他の目的のための単なる手段として使われてはならない（Kant[16]）．
- 何人も，その自由な同意なしに医学的又は科学的実験を受けない（Nuremberg Code[17], International Covenant[7] and Ovied Convention[18]）．
- 健康はすべての人々の平等な権利である（WHO[19]）．
- 研究参加者の権利と利益は新たな科学的知識を生み出すという研究の目的よりも優先する（DoH[1]，CIOMS[10] and ICH-GCP E6(R3)[20]）．

●尊厳，自律，善行，正義の尊重はすべての研究に適用される（Beauchamp & Childress[21], Belmont Report[22] and UNESCO[9]）.

2．ヘルシンキ宣言2024年改訂[1]に向けたグローバルな議論[23–24]から導かれる基本的原則

●研究参加者は自身の最善の利益と権利について決定する権利があり，それは参加者間，参加する選択をした人としない人との間で平等に共有されるべきである．研究参加前と参加終了後においてもその権利は平等でなければならない.

●研究データのインテグリティは確保されなければならない．社会的価値を生む研究結果は透明性と説明責任も公平に共有されなければならない.

●研究によるベネフィットへのアクセスは，世界中の必要とするすべての人々に保証されなければならない.

●研究倫理委員会，インフォームド・コンセント手続きからなる確立された研究ガバナンス・フレームワークにより，継続的な能力構築と新たな研究環境への対応を確保しなければならない．これには，各参加者の文化的背景を尊重した結果の普及，国際基準に適合する公的データベースを通じた研究情報の公正かつタイムリーな開示，ヘルスデータベースとバイオバンクの頑健なガバナンスが含まれる.

3．患者・市民の提案による将来志向の原則[5]

●研究開発計画の超早期からの一般市民の意義ある参画によって，標的集団に対するインパクトを，社会的，グローバルな文脈で，未来世代も視野に入れ，検討する.

・研究対象となる人々に対するダブルスタンダード，差別，スティグマ化を禁止する.
・国連の持続可能な開発（SDGs）[6]を目標とする.
・未来世代，環境，社会に対するインパクトを評価する.

●医師によって作成され医師に向けられた自律的規範としての倫理原則の視野を超えて，患者市民の視点を強化する.

・二重否定の表現を避けることを含み，平易な言葉を用いる.
・規範の適用範囲として，研究対象となる胚，胎児，死者の尊重について明記する.
・研究のすべての段階における患者市民参画を確保する.
・ピアサポーターを含む多職種協働.
・インフォームド・コンセントに基づくシェアード・デシジョンメーキング.
・研究倫理委員会（REC）の構成の多様性，公正性，公平性.
・RECsへの支援と独立性の強化.
・身寄りがなく同意能力がない個人の尊厳と権利を守る.
・すべての関係者に合意されるグローバル研究倫理規範を作成し，それらを国連（UNESCO，WHO），CIOMS，WMAなどの機関が採択する.

Items B：意義ある参画

WHOによる「意義ある参画」の以下のような定義と原則に従うべきである：「「生きられた経験」を持つ個人を，敬意と尊厳をもって公平にプロセスや活動に包摂し，その専門知識を評価し，権限を移譲し，健康アウトカムの向上を目指すこと．これには，特定の状態や問題を直接経験した人々と共に解決策や方針を共創し，その人々の課題を解決するためのプログラム／研究の計画から実施段階に至る意思決定において，その人々が中心的な役割を担うことを保証することを含む．」（WHO 2023[13]）（Appendixのprinciplesを参照．）

「私たち抜きで，私たちのことを決めないで」[25]というメッセージを認識し，健康関連の研究を，エンパワメント，「解放（emancipation）」[26]，ケイパビリティ[27]，そして「連帯（solidarity）」の行為として，誰一人取り残すことなく（SDGs[6]）推進するため，以下の事項を実践しなければならない：

1. 構造的な不平等を認識し，その克服に努める協力的なパートナーシップを確立し，研究によるベネフィットへのアクセスを確保するとともに，不利な立場にある個人のベネフィットを促進する（UNAIDS 2021[11]）．
2. 体系的な教育プログラムを通じて，効果的かつ責任ある参画（例：意思決定権を持つ）を確立する．
3. 自律的な意思決定が困難な人々の参画を擁護する．
4. 方針決定に参画する人々の多様性は，開かれた公正な公募を通じて確保されなければならない．

（下線は，実質的な行動変容が必要となる重要項目．）

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Appendix Infographics related to Item A and Clarification of principles of the WHO 2023 for Item B, provided by the Philippine Health Research Ethics Board

<Key Principles of Meaningful Engagement (lifted from WHO material, reference No. 13)>
The WHO emphasizes several key principles for meaningful engagement:

●**Dignity and Respect:**
Acknowledging the intrinsic value of individuals with lived experience and their inherent rights.

●**Power and Equity:**
Transferring power to people with lived experience, ensuring equitable inclusion in decision-making at all levels of policy-setting, design, and implementation.

●**Inclusivity and Intersectionality:**
Recognizing the diverse perspectives within communities of people with lived experience.

●**Commitment and Transparency:**
Sustained, transparent engagement processes where intentions and actions are clear.

●**Institutionalization and Contextualization:**
Integrating meaningful engagement into the structures and systems of organizations and governments.

Why It Matters

●**Better Outcomes:**
Programmes and policies (including researches) co designed and co-produced with people with lived experience are more likely to be effective and sustainable because they are more responsive to needs and barriers.

●**Expertise from Experience:**
Lived experience is viewed as a crucial form of expertise, offering unique insights into barriers, solutions, and program effectiveness that others may not possess.

●**Rights-Based Approach:**
It aligns with the human right of people to participate in decisions that affect their health and well-being.

Opinions on Items A & B

・A continuous effort in which patients and citizens work toward solving issues related to illness—free from constraints imposed by funding or political pressure—so that the value created through their activities is returned to everyone affected by the disease, and society as a whole deepens its understanding and interest in the illness.

(Comments provided with endorsement)

・The Declaration on Global Research Ethics and Meaningful Engagement represents an important step forward, as it aligns with this vision by explicitly including language requiring consideration of a global ethical perspective in all scientific research.

Items A

・Ensure an equitable distribution of the benefits generated by research.

・Continued dialogue to maintain trust in global research is critical. As new technologies and

modalities emerge, novel ethical challenges arise that should be addressed to ensure ethical practices and integrity of data and science for the society.
- Is there an international body that can address complaints of communities/people that have been unfairly treated as research participants by researchers from another country?
- In research involving human beings, the unconditional protection of the research subject must be unquestionable, inviolable and ethical by the country of origin of the study.
- At least, we should learn basic philosophy and ethics at the university level. (Translated from a comment in Japanese)
- It is very important to propose a Global research ethics for patients, participants and public.
- I think it´s very important having a global research ethics framework. In Brazil we have a consolidated system of ethics in human research, but right now we are under big pressure by the BigTechs on the legislation about Clinical Research.
- I believe that ethical considerations regarding the use of AI in healthcare should also be included in the Global Research Ethics.

(After August 25)
- Prerequisite items
- Congratulations on the necessary and thought-provoking debate. Considering the universality of ethics, which transcends physical territorial barriers and shares fundamental principles for all peoples, how do you assess the possibility of building a unified global research ethics evaluation system? Considering the diversity of countries in the global North and South, are we close to a common ethics evaluation system? What stage would we be at?
- It's very important to guarantee the best research!
- Research Ethics is a global issue. Experimental Research involving humans is fundamental to technological development, yet it is unacceptable for humans to be used irresponsibly. Human beings must be treated with respect. They cannot be used, but rather invited to participate in research.
- Unified global ethics standard.
- Core global ethics prerequisites drawn from declaration of Helsinki.
- I would like to know the guidlines of the Global Research Ethics.
- Civic Panel is needed to be established.
- I believe global research ethics are crucial because science should never advance at the expense of human dignity or fairness. While standards may differ across cultures, there should be a shared commitment to integrity, transparency, and protecting participants worldwide.

(Comments provided with endorsement)
- equitable engagement in research process should be ensured. equal access to research output and products should be available to all especially the vulnerable and low-income countries.
- This document is perfect and is necessary to protect participants in clinical research involving human beings.
- Ensure that all countries that have had research participants are offered affordable purchase in cases where the drug is registered. Ensure that human biological material is always non-patentable.
- Harmony. Living together or cohabilitation and Honesty are needed as norms.

- I recognize that the benefits of research should be distributed justly and must not be confined to privileged participants or communities. The commitment to the ethical principle of justice, which obligates us to consider how any successful interventions or products developed from research will be made reasonably available to the study population and the wider community, particularly in low-resource settings. This should be part of the ethical approval process.
- Equitable access to healthcare resources means affordable prices are set for low-resource communities and vulnerable populations. Here I stress on equity and not equality as the availability of drugs in Low-resources countries the same price as High-income countries will not benefit those communities who can not afford the cost.
- Engagement in research and policy making should be available and sought for every human research study. The research should be designed to fit the societal needs and directed to those who can benefit from the research outcomes
- Integrity of research: Reproducibility of research must be ensured, especially in clinical trials. Reproducibility means having detailed methods and statistical codes, so that anyone can repeat the analysis and verify the integrity of the data. Disclosure of data is also essential for clinical trials.
- Concern about involvement of healthy participant in case-control study
- How to protect the rights of "meaningful engagement" and "access to research benefits sharing" of children and adults with various mental health problems and participants from ethnic minorities in medical research?
- I believe that this initiative represents an important step toward strengthening shared ethical values in scientific research and ensuring meaningful and equitable engagement at the global level. It also supports the role of international organizations such as UNESCO, WHO, CIOMS, and the WMA in promoting these principles.
- The patient engagement and involvement on research lifecycle is very important to reduce the gap between needs and results of research. The respect, correct and right information, placebo/comparator etc are the key concept of changement in R&D.
- Protecting research participants by providing information and addressing their needs is our institutional purpose. Congratulations to these individuals who altruistically volunteer for research that respects them for maintaining ethics.
- Dear Distinguished Organizers of the GREEN Statement, It is an honor and a privilege to have been part in this project of profound relevance to global research. I sincerely appreciate the opportunity to have collaborated and learned alongside a team of professionals so dedicated and passionate about ethics in medical research.
  Every exchange of ideas has strengthened my conviction about the positive impact we can achieve from the academic sphere.
- As a professor at the University of Concepción (Chile) and legal advisor to the institutional scientific ethics committee, I have witnessed the fundamental importance of these principles for both training new generations of researchers and developing responsible science.
- I reiterate my gratitude for this enriching experience and for your exceptional leadership in promoting a dialogue so necessary for our work.
- It represents the vision of powerless populations all over the world specially the global south.

Items B

・For meaningful engagement, we need to communicate with more researchers.
・How do we ensure that community engagement comes from the community?
・To organise several free public lectures for the local community. You can also observe local public meetings, e.g., city council meetings. (Translated from a comment in Japanese)
・The purpose of study must also resonate with patient's needs.
・It involves actively involving patients, the public and the community in decision-making processes that impact their health, lives, and environments. Thia approach values lived experience equally with clinical or institutional expertise, ensuring that their voices will help shapei policies, research priorities, and service design.
・Active listening, collaboration spirit and constructive engagement with continuous education plus competencies building and partnership.
・"Meaningful engagement" means an alignment of purpose and mutual trust between researchers and participants.
・In research, research subjects, the general public and the community must be protected by each provision of the Nuremberg Treaty and the Universal Declaration of Human Rights.
・This means that patient, public and community have the right to meaningfully participate in all phases of research, from development to access to safe and efficacious products.
・I think that once community in Brazil represents potential participants of research, people should be engaged with discussion about research ethics. The patient needs to know the rights when participating in research, including the risks involved of its participation and their obligations to researchers.
・"It is essential to consider the following elements;
  ✓ Fairness: We value ensuring all individuals have the opportunity to participate.
  ✓ Collaborative Problem-Solving: We prioritize fostering partnerships where all stakeholders are treated equally.
  ✓ Shared Responsibility: We believe that each individual assumes the duties that align with their role."
・I believe meaningful engagement involves active collaboration with patients, public, and community throughout the research process to ensure that their perspectives and experiences shape decisions and outcomes.

(After August 25)

・Public and patient engagement is very important in order to reduce the gap between the needs and results of research
・Meaningful engagement is a process that requires great care; participants must be encouraged to actively participate, from the development of the research design to the analysis of the results. Organizing participants is also crucial, since from a political, economic, and social perspective, participants constitute the most vulnerable group of a research endeavor.
・Involve not only the participants but also broader community especially in clinical trials.
・I think thier apprival to participate in the research and the importance to conduct research that have impact on them.

・To know each other and enhancing the value of drugs or therapy.
・Independence of Civil Panel is essential.
・Meaningful engagement is authentic, respectful, and impactful involvement that gives patients, the public, and communities a real voice in shaping research and health decisions.

(Comments provided with endorsement)

・I agree that education is a fundamental and important right. However, I believe there are still people who lack access to sufficient education. We should be careful to ensure that such individuals are not restricted from participating in research ethics committees or discriminated against in any way because of their lack of education. I believe it is desirable to consider research ethics in a way that includes these people. We should also be mindful that those with and without education don't end up criticizing each other. I hope that all people can participate in order to mitigate the effects of cognitive biases that can arise from what is known.
・“Nothing about us, without us” is the result of empowerment process of the community and of individuals. I suggest to add the term "empowerment" in the Item B for meaningful engagement.

Other aspects

・Inclusion in future activities the development of AI Governance framework for global research.
・Do you intend to refer to IMI PARADIGM PGMS work which has looked at cross cultural aspects in EDI and PPIE?
・In Brazil it is forbiden to receive any payment for participating in research. What is the global research ethics committee’s position on this??