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GREEN Statement: Global efforts towards the highest ethical standards in research involving human participants

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Abstract

The GREEN Statement (”The Statement for **G**lobal **RE**search **E**thics **N**orm and Meaningful Engagement”) was first announced on 17 September 2025, as a consensus developed through ongoing global discussions, culminating in the international symposium of the Japanese Association for Philosophical and Ethical Researches in Medicine (JAPERM), held two days before the announcement. Its objective is to urge international organisations engaged in the development of international standards of research ethics to incorporate the elements of our Statement to achieve the highest standards of research ethics.

This paper outlines the background and content of the GREEN Statement, the outcomes of its publication, including global approval statistics, as well as the ensuing discussions within the relevant communities. It also presents future perspectives for pursuing the highest ethical standards, including the quest for peace and a sustainable society.

Key words

global bioethics, research involving human participants, health databases and biobanks, patient public involvement, sustainable development goals (SDGs)

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Introduction

The organisers of the GREEN Statement, authors of this paper, held a symposium on September 15, 2025, titled: ”*Transformation of the global research ethics: the 2024 revision of the Declaration of Helsinki to promote patient engagement and dynamic consideration on vulnerability*”. It was one of the open call sessions at the Second International Conference of The Japanese Association for Philosophical and Ethical Researches in Medicine (JAPERM), held at Kanagawa University, Yokohama, Japan. “The GREEN Statement”[1] was finalised on 17 September 2025 as the result of the three sequential international meetings: (i) a webinar on August 25; (ii) a hybrid (online/in-person in Tokyo) meeting on September 13, both supported by JAPERM; (iii) and finally the aforementioned JAPERM symposium[2]. The proceedings of these meetings were published in the medical journal *Clinical Evaluation*, Vol. 53, No. 2, December 25, 2025[3].

The full name of the GREEN Statement is ”*The Statement for **G**lobal **RE**search **E**thics **N**orm and Meaningful Engagement*”. The objective of the Statement is to call upon the international organisations listed below, engaged in development of each respective international standard of ethics in research involving human participants, to incorporate the elements clarified in the Statement. This is to achieve the highest ethical standards to protect the rights of research participants and communities and to promote the social value of research. This set of elements also includes principles for “meaningful” participation in research. In addition, our ultimate goal is to establish legally binding global research ethics norm in the form of a Global Convention.

- The World Medical Association (WMA). the Declaration of Helsinki[4] (DoH);
- The Council for International Organizations of Medical Sciences (CIOMS). International ethical guidelines for health-related research involving humans (CIOMS Guidelines)[5];

  and as specialized agencies of the United Nations:
- The United Nations Educational, Scientific and Cultural Organization (UNESCO). Universal Declaration on Bioethics and Human Rights[6]; and
- The World Health Organization (WHO). WHO framework for meaningful engagement of people living with noncommunicable diseases, and mental health and neurological conditions[7].

The reference models for achieving the ultimate goal of the Statement are the following two international conventions: the first established a bill of human rights including only one article to prohibit human experimentation without consent; the second established a charter of human rights for participants in research but limited to signatory member states of the Council of Europe.

- United Nations. International Covenant on Civil and Political Rights[8].
- Council of Europe. Convention on human rights and biomedicine[9].

The GREEN Statement was announced, with a call for endorsements until the end of October 2025, and was published in the aforementioned issue of *Clinical Evaluation*(1), with the names of 91 individual endorsers, including 17 institutional endorsements from 19 countries, along with their views.

This paper outlines the background and contents of the GREEN Statement, the results of its publication, and future perspectives.

1. Historical context of the GREEN Statement

The full text of the GREEN Statement, originally written in English and translated into Japanese and Arabic, is available in *Clinical Evaluation*[10]. The global debates that led to the Statement were originally directed toward the 2024 revision of the DoH. The GREEN Statement was published based on the two previous statements: "Helsinki Statement"[11], and "Patient Public Declaration of Research Ethics"[12], and the two books that provided their rationale[13],[14]. The building consensus and its methodological aspects are described below, in reverse chronological order.

- **The 2024 Declaration of Helsinki: Global Efforts Towards the Highest Ethical Standards**(14):
    - 17 September 2025 (Same date as the finalisation of the GREEN Statement)
    - A book which gathered commentaries with critical views on the 2024 revision of the DoH. Leaders of the WMA provided two forewords. The chapters are divided into three parts: Perspectives of Global South and Asia; Prospects for the future; and Alternative framework. The final chapter concludes by emphasising the need for a highest ethical global standard, subsequently presented in the GREEN Statement.
    - The contributors to this book have been engaged officially, collaboratively, or externally, in the 2024 DoH review process, which began in April 2022.
- **Three Sequential Meetings: Consensus for Global Research Ethics and Meaningful Engagement**(3):
    - 25 August (webinar); 13 September (hybrid); 15 September (in-person), 2025
    - Consensus development for "Global Research Ethics Norm and Meaningful Engagement", later named "GREEN Statement".
    - At the first meeting (webinar), Bioethics Working Group of Japanese Institute for Public Engagement (Ji4pe) introduced their "Patient Public Declaration of Research Ethics." Brazilian group Juliana Barbosa Research Participant

Protection Institute, created in May 2024, presented their mission of defending the rights of research participants. With researchers/specialists made presentations and discussed with all about “What is meaningful engagement”.

  - At the subsequent (hybrid) meeting, the GREEN Statement Organisers and members of Ji4pe met in Tokyo, broadcast globally, and discussed the GREEN Statement line by line, and agreed on its contents. A representative and members of the Egyptian Network of Research Ethics Committees (ENREC) joined online, expressed their endorsement to the Statement and provided an Arabic translation.
  - At the third meeting (JAPERM symposium) in Yokohama, GREEN Statement Organisers and one Japanese patient representative discussed with JAPERM participants.

- **Helsinki Statement from an Independent Stakeholders’ Group to Expand the Impact of the 2024 Revision of the WMA Declaration of Helsinki**(11):
  - 18 October 18 2024
  - A statement clarifying 10 improvements and 5 outstanding challenges in the 2024 revision of the DoH.
  - Four of the five organisers of the Helsinki Statement (same as the GREEN Statement organisers) attended the General Assembly of the WMA in Helsinki, held two times of meetings broadcast worldwide from Helsinki, and issued the Statement one day before the WMA adopted 2024 revision of the DoH. The Statement clarified 10 improvements, including engagement of participants/community in all stages of research; inclusion of vulnerable people with increased protection and benefit sharing; and additional requirements to adhere to the WMA’s Declaration of Taipei (DoT) on health databases and biobanks[15], if data obtained in research may be used for undefined future purposes. The Statement also criticised weakening of the restriction to placebo use when an active control exists, and the weakening of the already precarious guarantee of post-trial access to the study intervention for participants who still need it after the completion of the trial. The Statement received endorsements of 125 individuals, including five institutions in 24 countries, and the published Statement was shared with the WMA. The Statement was translated and published in Japanese, Arabic and Greek[16].
- **Patient Public Declaration of Research Ethics: Research ethics of the people, by the people, for the people: Expanding the impact of the 2024 revision of the Declaration of Helsinki**(12):
  - 10 October 2024
  - A Declaration prepared by the Bioethics Working Group of Ji4pe based on their

  views on the 2024 revision of the DoH.
  - Based on more than five years of monthly online meetings of a group of patients and the public, their views were addressed to the global research ethics community through publications and webinars, involving the WMA, and were finally consolidated into this Declaration.
- **Ethical innovation for global health: pandemic, democracy and ethics in research**(13):
  - 14 November 2023
  - This book aims to identify elements for Ethical Innovation for Global Health scrutinising the COVID-19 pandemic, and is composed of the three parts: Perspectives of Global South and Asia; Historical and forward-looking perspectives for international ethical principles; Alternative framework for Ethical Innovation for Global Health.
  - The contributors of this book were mostly speakers at the webinar held in June 2021, during the COVID-19 pandemic[17]. Participants, including representatives from the WMA, discussed principles of research ethics, especially regarding the ethics of placebo-controlled trials and the right to post-trial access in the context of the pandemic, which have been the most critical items of the global disagreements in the DoH. This webinar highlighted structural inequities, according to which the most vulnerable were disproportionately affected by the pandemic, while vaccines were developed based on global placebo-controlled trials in affected regions, the benefits were disproportionately distributed to the wealthier regions.

The starting point for the above initiative was a symposium at the Japanese Society of Clinical Pharmacology in Tokyo, held on 4 December 2019, where Dirceu Greco gave a lecture on the history that led to the 2013 revision of the DoH and the challenges for the future; and Otmar Kloiber, Secretary General of the WMA, spoke about the importance of the WMA Declaration of Taipei on Health Databases and Biobanks, which complements the DoH as a basis for data-driven research[18].

2. Contents of the GREEN Statement

The composition and elements of the GREEN Statement are shown in Table 1, which is a brief summary.

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Table 1 The composition of the GREEN Statement (brief summary)

Set of items to be included in the
Global Research Ethics Norm (Items A) and Meaningful Engagement (Items B)

Items A: for Global Research Ethics Norm[19]

1. Fundamental norms referred to as the bases of research ethics

- First, do no harm (Hippocrates[20])
- Human beings must not be used as a mere means to an end (Kant[21]).
- No one shall participate, without free consent, in medical or scientific experimentation (Nuremberg Code[22], International Covenant[8] and Oviedo Convention9).
- Health is an equal right for all (WHO[23]).
- The rights and interest of research participants prevail over the research objective of generating scientific knowledge (DoH[1], CIOMS[5] and ICH-GCP E6(R3)[24]).
- Respect for dignity, autonomy, beneficence (Beauchamp & Childress[25], Belmont Report[26] and UNESCO[6]).

2. Fundamental principles derived from the global discussions(13, 14) on the revision of the 2024 DoH

- Research participants' best interest and equal rights, during, before and after completion of research.
- Research integrity and social value with transparency and accountability.
- Access to benefits from research.
- Already established research governance framework: research ethics committees (REC); informed consent procedures; study registration in public database, etc.

3. Forward-looking principles defended by patients and the public(12)

- Global context and for future generations
  - Prevent double-standards, discrimination or stigmatisation.
  - Aim for the United Nations' Sustainable Development Goals (SDGs)[27].
  - Assess the impact on future generations, the environment, and society.
- Strengthening patient/public perspectives on the ethical principles.
  - Use plain language.
  - Respect for embryos, foetuses, and deceased persons.
  - Patient public involvement in all phases of research.
  - Multidisciplinary collaboration: including patient peer supporters.
  - Shared decision-making based on informed consent.
  - Diversity, fairness, equity and independence of the REC.
  - The rights of individuals incapable of consent who have no available relative.

Items B: for Meaningful Engagement

The definition and principles of "meaningful engagement" referring WHO[28].

"Nothing about us, without us"[29], to make health research an act of empowerment, emancipation[30], capability[31] and solidarity. leaving no one behind (SDGs), following items implemented into practice:

1. Access to the benefits of research.
2. Responsible participation, through systematic educational programmes.

3. Advocate for the participation of people with difficulties in making autonomous decisions.
4. Open and fair recruitment of participants in policy making.

The Items A refer to the Global Research Ethics Norm, derived from global discussions for the 2024 DoH, which consists of three parts:

1. Fundamental norms already established. The clear positioning of these items is needed for the robust establishment of a Bill of Rights for research participants.
2. The items derived directly from the discussions for the revision of the 2024 DoH. Equity in all types of research, including placebo-controlled trials, and the guarantee of post-trial access are fundamental. No participant can be excluded from the physician's obligation to provide the best proven intervention, a fundamental principle established by the WMA, but which now, needs to be reviewed due to the weakening of principles of placebo-controlled trials and post-trial access. Furthermore, the principles and procedural aspects of the established framework, such as, research ethics committees, the process of informed consent, and publication of research in public databases, are also clarified in this section.
3. The items presented in the Patient Public Declaration of Research Ethics, which are prospective, are not well discussed in the DoH and CIOMS Guidelines.

Items B refers to Meaningful Engagement, which has not been well established in current practice of several regions. Although the principle has already been clarified by WHO and other organisations, we must achieve a more rigorous trajectory to guarantee post-trial access and benefit sharing, through "meaningful" engagement of participants and the relevant communities. To achieve this goal, responsible participation through a systematic educational programme, respect for people with limited capacity, and open public recruitment in the policy-making process are crucial.

3. Results of the GREEN Statement

3.1 Geographical distribution of endorsers

Table 2 shows the geographical distribution of endorsers of the GREEN Statement, compared to the previous initiative, known as the Helsinki Statement.

Table 2 Geographical distribution of endorsers of the GREEN Statement, compared to the Helsinki Statement

		Helsinki Statement		GREEN Statement	
	# of	Individuals	Groups	Individuals	Groups
Africa (global south)	**Egypt, individual**	**9**		**7**	
	Egypt, in a group	**32**	**1**	**4**	**4**
Asia	**Japan, individual**	**30**		**10**	
	Japan, in a group	**7**	**2**	**12**	**2**
Latin America (global south)	**Brazil**	**17**	**0**	**10**	
	Uruguay	**4**		**1**	
	Mexico	**3**		**1**	
	Argentina	**2**		**1**	
	Panama	**1**			
	Chilie-Brasil	**1**		**1**	
	Guatemala	**1**			
	Jamaica	**1**			
(GREEN only)	**Chille**			**1**	
	Brazil, in a group			**7**	**7**
	Mexico, in a group				
	Argentina, in a group			**1**	**1**
Africa (global south)	**Kenya**	**1**		**1**	
	South Africa	**1**		**1**	
	Tanzania	**1**		**1**	
(GREEN only)	**Egypt-Saudi Arabia**			**1**	
	Tanzania, in a group			**1**	**1**
Austraria	**Austraria**	**1**			
Europe	**Belgium**	**1**	**1**		
	Greece	**1**		**1**	
	Netherland	**1**			
	Czech Republic	**1**			
	Norway	**2**			
(GREEN only)	**Germany, in a group**			**1**	**1**
	Italy			**1**	
	Poland-Japan			**1**	
	UK-Greece			**1**	
	Switzerland			**1**	
North America (GREEN only)	**United States**			**1**	
Asia	**Philippine**	**3**	**0**	**1**	
	Pakistan	**1**			
	Nepal, Group	**1**	**1**		
	Turkey	**1**			
	South Korea	**1**			
(GREEN only)	**Philippine, in a group**			**22**	**1**
		125	**5**	**91**	**17**

Helsinki Statement		
Global South	**74**	
Asia	**44**	
Europe	**6**	
Austraria	**1**	
	125	**Individuals**
	5	**groups**
	24	**Countries**

GREEN Statement		
Global South	**39**	
Asia	**45**	
Europe	**6**	
North America (US)	**1**	
	91	**Individuals**
	17	**groups**
	19	**Countries**

Both Statements clearly suggest the participations of alternative and underrepresented voices from the Global South and Asia. Particularly in the case of the DoH, concerns against American influence were expressed during a webinar we organised [32]. Through more detailed discussions among relevant communities, the

Mediterranean region and Southern Europe also appear to be aligned with a framework that respects human rights, while North America and Northern Europe, due to their emphasis on empirical science, appear to be aligned with a utilitarian ethic that prioritises the advancement of science[33].

3.2 Subsequent discussions that followed the publication of the GREEN Statement

Following the publication of the GREEN Statement, we had significant interactions with the European Patients' Academy on Therapeutic Innovation (EUPATI) in February 2026, and a session with CIOMS is also planned for May 2026. Regarding the discussion with the WMA our debates are shifting from the DoH to the DoT, as the latter began its revision process in April 2025. Therefore, we are exploring potential remaining challenges to strengthen the GREEN Statement, reflecting these recent discussions.

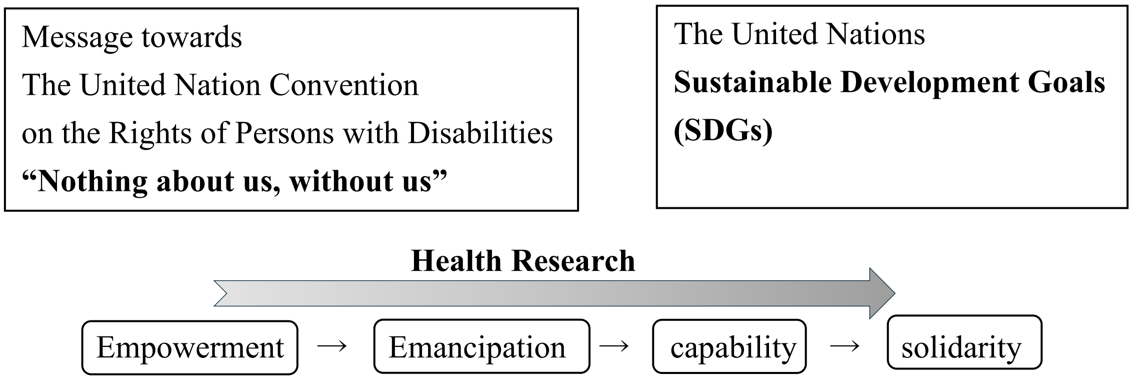
- **EUPATI**

The GREEN Statement Organisers and the Bioethics Working Group of Ji4pe held an online meeting on February 4 to hear feedback from EUPATI members on the Statement. This was because one of the EUPATI members who endorsed the Statement offered constructive opinions on the "meaningful" engagement, during the consensus-building process of the GREEN Statement.

Her advice was to strengthen the steps in the trajectory of health research towards the United Nations SDGs. She proposed adding two steps called "empowerment" and "capability,"31 to the already proposed steps from "emancipation"30 to "solidarity", as shown in the Figure 1. She also provided supporting literature by Amartya Sen for the term "capability"(31). The addition of these two terms is very important for the following reasons:

- "Emancipation" means that oppressed, vulnerable people learn from their own motivation, presenting a dynamic "bottom-up". Meanwhile, "empowerment" means that experts provide education to non-experts, suggesting a "top-down" procedure. Even so, it is important to incorporate "empowerment", because there would be some people who cannot emancipate themselves without the opportunity of receiving education.
- "Capability" is also a crucial aspect of human potential; people's well-being is not determined by what they already possess, such as wealth or resources, but rather by what they can achieve through education and social participation. Participation in research can also contribute to the SDGs, leveraging this capability and promoting "solidarity" with others.

Figure 1. Steps in the trajectory of health research towards the United Nations SDGs.



During the meeting on February 4, EUPATI stated that “*GREEN Statement and EUPATI share a common foundation: recognising patients as equal partners in research and medicines development*”, and “*Both promote a shift from tokenistic involvement to structured, meaningful engagement, embedded in governance, ethics, and decision-making processes*.”[34] A group of Japanese patients raised several relevant questions about the European educational system for patients and the general public. EUPATI presented its development history since 2012, within the framework of the European Commission’s Innovative Medicines Initiative (IMI). There has been substantial public support for improving patient understanding and strengthening involvement in drug research and development.

- **CIOMS**

The session with CIOMS representatives is planned for May 2026. The GREEN Statement Organisers have prepared presentations that highlight the following key points for discussion with CIOMS representatives:

(1) The GREEN Statement aims to establish the highest standards of research ethics as legally binding global norms, such as a Global Convention, based on global discussions to expand improvements and rectify deficiencies in the 2024 DoH.

(2) Achieving the above objective will take considerable steps and time. For this reason, the GREEN Statement aims to function as a “soft law” and educational material to enable decision-making and actions geared toward the highest ethical standards in research practices and research review.

(3) The highest ethical standards are logically simple, understandable to patients and the general public, and for various interested parties to work toward them. We must avoid flaws such as the placebo and access clauses of the DoH, which resulted in guidelines that were complicated by being a compromise, and that did not protect the rights of participants.

On the other hand, the CIOMS Guidelines provide an interpretation of the DoH to be applied in resource-limited settings. Consequently, the most controversial items such as placebo-controlled trials and post-trial clauses represent a higher ethical standard than that of the DoH, as discussed in the items (i) (ii) below. However, there is room to include recommendations from patients and the public, as suggested in (iii). Also, the standards established in Items A-1 in the GREEN Statements are necessary, as argued in (iv) below.

(i) From an ethical standpoint, placebo-controlled trials should be restricted to cases where there is no proven intervention; this principle was clearly established in the 2000 DoH and is upheld in most Latin American countries that host global clinical trials. However, in response to arguments that applying this principle is difficult for economic and practical reasons, the DoH stated that placebo-controlled trials, even when a proven intervention exists, the use of placebo is permitted if it does not "increase the risk of serious or irreversible harm". The CIOMS guidelines reduced this acceptable risk to "minor increase above minimal risk". This was an acceptable compromise even for the Uruguayan Medical Association, which had presented tabled a motion opposing the placebo clause in the final version of the 2024 DoH.

(ii) The right of access to efficacious and safe study interventions by those who still need it after the completion of the trials was established in the 2000 DoH, but was downgraded for the reasons already mentioned above. Although the CIOMS guidelines also do not guarantee access, they establish key points on strategies to achieve it through community engagement. However, based on our experiences with the HIV/AIDS and COVID-19 pandemics, more effective strategies must be prescribed: such as the principles agreed upon in international treaties, which prioritise responding to public health crises over protecting intellectual property rights[35]; the importance of technology transfer and the development of manufacturing capacity[36],[37]; and that health products during the crises are guaranteed as "global public goods"[38],[39],[40],[41].

(iii) Furthermore, the perspectives of patients and the public must be respected: To ensure that research must have "social value", the research objectives must be adjusted towards the SDGs; to avoid the risks of the impact of research results on society and spirituality and potential for harm to specific groups, which has recently attracted attention in leading journals[42]. Take into account the possible impact on future generations[43]; the participation of the general public in research ethics committees (RECs), ensuring diversity through open recruitment for the appointment of REC members; and the advocacy for people without relatives who have no one to act on their behalf in decision-making.

(iv) The GREEN Statement in Item A.1 clearly sets out the well-established indispensable ethical principles. Although previous versions of the CIOMS

Guidelines included references to established international human rights norms and the Belmont Report, they were omitted in the 2016 Guidelines. Numerous references are provided in other CIOMS documents to assist readers who wish to explore the topics in greater depth. With regard to the principles of research ethics, it is necessary to explicitly state that these ethical principles are based on international norms to ensure the fundamental rights of all human beings, having been established over a long history.

- **WMA**

Discussions about the WMA principles are focusing more on debates about the WMA's DoT rather than on an exchange of views about the GREEN Statement. This may be because the WMA initiated the revision process of the DoT in April 2025[44]. The DoT is a set of ethical principles for health databases and biobanks, which must also be applied in the development and use of artificial intelligence (AI)[45] that utilises large volumes of personal data. The organisers of the GREEN Statement believe that the highest ethical standards must be pursued in the ethics of health databases and biobanks, incorporating the perspectives of the Global South, vulnerable people, patients and the general public. To that end, as part of the IFAPP webinar series, we plan to convey these views to the WMA[46][47], beginning with a webinar with WMA leaders[48].

During this process, extremely serious disputes affected the discussions on the revision of the DoT. In the 2016 revision of the DoT, the South African Medical Association (SAMA) played a key role in reflecting the perspectives of the Global South. However, SAMA withdrew from the workgroup for the current revision process because the Israel Medical Association (IMA) which chairs that workgroup[49],[50], did not take a stand against the atrocities of Israel's attacks against the population of Gaza.

In the 2016 revision process of the DoT, SAMA proposed the inclusion of a "material transfer agreement (MTA)" in the the DoT's governance framework. This stems from concerns that high income countries (HIC) may acquire data and biological materials from low- and middle-income countries (LMIC) in an exploitative manner, without a valid agreement of the material-holding countries, or under unfair conditions. On the other hand, genomic data collected within the recently established regulatory environment is skewed towards populations of European descent[51],[52]. This would lead to biased research results and inequality in distribution of benefits.

In addition, recently, a series of "immoral" bilateral agreements between African countries and the United States (US) have been rejected by African governments or criticized by global media. In these agreements they have to share biological resources, sensitive health data and pathogen samples, without any guarantee of access to the resulting medical innovations[53]. The US threatens to withhold HIV Aid unless Zambia expands access to critical minerals and to genetic sequence data of pathogens, together with people’s health data[54]. Furthermore, US Center for Disease Control (CDC) decided to fund a randomised-controlled study in Guinea-Bissau, proposed by the University of Southern Denmark, whose intention was to set a control group with delayed hepatitis B vaccination for new-born babies, which goes against a well-established intervention. The study was suspended and, in response to criticism from the media and scientists[55], WHO declared it unethical [56]. Renowned ethicists have criticized that the current U.S. government for apparently trying to find risks in vaccination to justify its Advisory Committee “*to abandon a 30-year recommendation that all babies born in the U.S. be vaccinated for hepatitis B at birth*”[57].

SAMA would certainly play a key role in addressing such critical issues, however, it does not participate in the workgroup for the revision of the DoT, due to the suspension of its official relationship with the IMA(49, 50). The South African government has filed a complaint with the International Court of Justice (ICJ), alleging that Israel’s attacks on Gaza constitute genocide and violate the Convention on the Prevention and Punishment of the Crime of Genocide[58]. On 26 January 2024, the ICJ issued provisional measures ordering a halt to all acts constituting genocide[59]. SAMA also asserts that the IMA President justified the attacks on hospitals and civilians in Gaza for the same reasons presented by the Israeli government, namely, that these facilities served as Hamas strongholds, which has never been proven and, in any case, would never justify the bombing of civilians and health professionals. If the IMA has any defence to present, it should communicate it to SAMA; the fact that the WMA continues discussions on the revision of the DoT with the IMA in the absence of SAMA, without providing any opportunity for dialogue to resolve the dispute, appears to third parties as if the WMA were indirectly endorsing the justifications of the Israeli government[60]. It is a necessary (though not sufficient) condition for normalising discussions on the revision of the DoT that the IMA and the WMA speak out against the Israeli government and take steps to end the Israeli attacks. Furthermore, all of us engaged in medical ethics must play do our part to end the atrocities[61].

3. Future perspectives

The organisers of the GREEN Statement have maintained their commitment to the diverse ethical issues encountered in the global research community, fostering global dialogues, issuing opinions on specific cases, and publishing short commentaries. As part of this process, we intend to publish scientific papers that address the challenges encountered and consolidate global debates through the publication of scientific articles/books, online/in-person meetings. Our ultimate goal in future is to establish Global Research Ethics Norm as a legally enforceable Global Convention.

Through the discussions we have had since the publication of the Statement, we have encountered three challenges that will be analysed in more detail:

(1) From protection to a bill of rights.

Facilitating publications and discussions to ensure that the GREEN Statement functions as soft law or educational material is not a difficult task and constitutes our immediate objective. Meanwhile, establishing it as a legally binding global ethical norm will require many steps and it is essential to clarify the ideal form. For meaningful engagement become a prima facie norm, as suggested by the Brazilian group of research participants, the convention must be designed to establish the rights of research participants, not limited to the concept of protection. During discussions on the GREEN Statement, we reaffirmed that the "Convention on the Rights of Persons with Disabilities"[62] and the "Declaration on the Rights of Indigenous Peoples"[63] have significantly transformed the world. We wish to establish the "Convention on the Rights of Research Participants" as our ultimate goal. Among the comments on the GREEN Statement, the question arose to ask "*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?*". Ideally, this could be the United Nations' Treaty Body, established by a Convention on the Rights of Research Participants, in collaboration with the UN Human Rights Council. To address situations such as the recent unethical proposal for Hepatitis B experimentation in Ginea-Bisau(55), as well as the immoral proposal for collection of samples and data in African countries, both under the power politics of the US government, the rights of participants of research, health databases and biobanks must be protected by an international body of this type.

(2) Databases, biobanks and artificial intelligence

The GREEN Statement originated from discussions for the 2024 revision of the DoH. Consequently, although health databases, biobanks and AI were within the scope of discussions during the consensus development, these items were not sufficiently mentioned in the Statement. Most of the items presented in the GREEN Statement are also directly relevant to the ethics of health databases, biobanks and AI. This fact must be explicitly stated within the scope of the GREEN Statement.

(3) Ethics to protest against wars

The ethics of research involving humans inherently contradicts war and it aims for the abolition of all forms of war and conflict, because the objective of research is to generate social value to improve people's well-being. We have witnessed many cases of complete destruction of the infrastructure essential for maintaining population health. It would be hypocritical to continue discussing research ethics while remaining silent on this issue[64]. We reaffirm this point, through ongoing discussions about what is happening in Ukraine, in Gaza, and other places in the world, in the context of research ethics. We believe that global research ethics norms inherently incorporate the pursuit of peace. Actions are needed to articulate this and translate it into practice. Such guidance has not yet been clearly defined in the language of research ethics norms. For this reason, the GREEN Statement must include a clear message of protest against war and actions in pursuit of peace.

Conclusion

The GREEN Statement is a consensus developed through global efforts to establish the highest standards of research ethics involving human participants. This Statement underpins our own research practices, research review processes, and our educational and awareness-raising activities. It provides core values for the global debate on research ethics. The path to concluding a Convention on the Rights of Research Participants is long and arduous. However, as research and development including cutting-edge technologies become increasingly global, structures of exploitation and injustice must be eliminated through global collaborative efforts. We will continue our collaboration to end wars and conflicts and to pursue a peaceful and sustainable society. Our continuing debates aim for the highest standards of research ethics and contribute to the emancipation of people in the fight for their rights.

Conflict of interests

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