A Statement for Global Research Ethics and Meaningful Engagement

(Draft as of Aug 21, 2025)

We are a global network dedicated to upholding the highest ethical standards for research involving humans, by protecting the rights and well-being of participants while by generating value in the process of solving global challenges. To this end, we encourage all interested parties to participate productively and meaningfully at every stage of the research process. We welcome io our network anyone who shares our goals and who is committed to mutual respect and cooperation among collaborators. The objective of this statement is to request that international organisations reflect our proposals for “Global Research Ethics and Meaningful Engagement”.

The World Medical Association's Declaration of Helsinki[1], one of the most renowned sets of ethical principles for research involving humans was first adopted in 1964 and underwent its 10th amendment in 2024. The latest revision recommends the engagement of research participants and their communities at all stages of research, including planning, implementation, and disseminating results. It also deplores structural inequalities in research and clearly defines a path to promote the participation of vulnerable participants, ensuring they are adequately protected and benefit from the research. Furthermore, with a focus on artificial intelligence (AI) research and development which extensively utilises personal data, it recommends adherence to the Taipei Declaration on health databases and biobanks[2] when reusing data or human biological samples obtained through research.

The “Helsinki Statement”[3], which supports the ten key points of the 2024 revision including the points aforementioned and clearly states its disagreement with the remaining issues, was published on 18 October 2024. As of November 2024 it had been endorsed by 125 individuals from 24 countries[4]
http://cont.o.oo7.jp/52pop/HelsinkiStatement_18Oct24_final.pdf

Additionally on 10 October 2024, the “Patient Public Declaration of Research Ethics” was launched[5]. Led by a group of patients and members of the public, it aims to promote the development of research ethics norms that consider the equitable participation of all interested parties, and address global social issues from the sustainable development goals (SDGs) [6], as well as the spiritual and social impacts on future generations, and the sustainability of ecosystems.
http://cont.o.oo7.jp/52pop/W28-W39.pdf

In response to these initiatives, we strongly recommend that organisations developing international research ethics documents[1,7,8,9] include the following items (see **items A below**) in future development

Furthermore, we will strive in each field and cooperate internationally to ensure that the "meaningful" engagement indicated in the Declaration of Helsinki and other international ethics documents[9], [10], [11] is realised in the implementation of the following elements cooperating internationally in each field. (**Items B below**). To this end, we have begun developing a consensus statement on the elements necessary for s "meaningful" patient and public engagement.

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

Items A: for Global Research Ethics[12]

- Human beings must not be used as a mere means to an end (Kant)[13].
- No one shall participate, without free consent, in medical or scientific experimentation (International Covenant)[14].
- Health is an equal right for all (WHO)[15].
- The rights and interest of research participants prevail over the research objective of generating scientific knowledge (DoH)1.
- Respect for dignity, autonomy, beneficence and justice all apply in the research context (Beauchamp & Childress[16], Belmont Report[17]).

2. Fundamental principles derived from the discussions on the DoH1:

- Research participants are entitled to determine their own best interest and rights, which should be shared equally between participants and those who chose not to participate in research. There must be equality of rights before inclusion and after completion of participation.
- The integrity of research data must be ensured and results must be shared equitably, with transparency and accountability. Access to research results must be guaranteed for all those in need worldwide.
- Continuous capacity building and response to the emerging research landscape must be ensured by an already established research governance framework consisting of: research ethics committees, informed consent procedures; along with disseminating results to each participant respecting their cultural background; fair, timely disclosure of study information through public databases, adhering to international standards and robust governance of health databases and biobanks.

3. Forward-looking perspectives presented as patient and public opinions5:

- Early evaluation of the research and development plan, considering the impact on study target populations, society, global contexts, and future generations.

  - Avoid double-standards, discrimination or stigmatisation against the target populations of the study.
  - Aim for the United Nations' Sustainable Development Goals (SDGs).
  - Assess the impact on future generations, the environment, and society.
- Strengthening patient/public perspectives on the ethical principles beyond the scope of autonomous norms established by and addressed to physicians.
  - Use plain language, e.g., to avoid "double-negative" phrases.
  - The scope of the Declaration needs to adequately address respect for embryos, foetuses, and deceased persons for whom studies are performed.
  - Ensure the participation of patients and the public in all phases of research.
  - Multidisciplinary collaboration: including patient peer supporters.
  - Shared decision-making based on informed consent.
  - Diversity, fairness and equity in the composition of Research Ethics Committee.
  - Reinforce support for and independence of RECs
  - Protect the dignity and rights of individuals incapable of consent who have no available relative.
  - Develop international research ethics documents agreed by all the interested parties and backed up by such organisations as United Nation, UNESCO, World Health Organisation of CIOMS.

Items B: for Meaningful Engagement (This should be explored further between 25 August and 13 September meetings.)

1. Collaborative partnership acknowledging structural inequity and striving to overcome them and assuring access to research benefit whereas promoting disadvantaged individuals[10].
2. Active and responsible participation through systematic educational programmes.
3. Advocate participation of people with difficulty of autonomous decision.
4. Diversity of participants through open recruitment for fairness

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(Summon your participation)

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