

### 3. Conclusions and future perspectives: the Helsinki Statement

An overview of the 2024 revision of the DoH are outlined above. As noted in section 1.4, the authors published the “Helsinki Statement”<sup>26</sup> one day before the adoption of the DoH. In the first half of the “Helsinki Statement”, we praised 10 points which we considered improvements. In the second part of the “Helsinki Statement” we focused on the remaining challenges, including the items on placebo use and post-trial access, in accordance with Uruguay’s motions.

The “Helsinki Statement:” is an expression of the consensus of independent stakeholders who aim to expand the impact of the improved elements of the DoH and to work together to strengthen the protection and rights of research participants while ensuring the scientific integrity of research, and to implement the practice of conducting and reviewing research.

Among the signatories, those who have contributed sufficiently and agreed to be authors are “authors” and the others are “signatories.” The five people (Chieko Kurihara, Dirceu Greco, Kotone Matsuyama, Takeo Saio and Varvara Baroutsou) who were directly involved in the planning and implementation of the initiative were named as corresponding authors. The names of all individuals and countries have been included in the publication. The call for signatories has been distributed to the registrants of the two web symposia, mentioned above, as well as to international and national mailing lists and other interested parties and groups that the corresponding authors deemed appropriate. IFAPP distributed the information of the web symposia but did not distribute the information of “Helsinki Statement”, as this was not an official IFAPP activity. The period to receive endorsements was until 30 November (some agreements were made after this date). Table 3 shows the regional distribution of the signatories.

**Table 3 Regional distribution of signatories to the Helsinki Statement**

		Individuals	Groups
Africa (global south)	Egypt, individual	9	
	Egypt, in a group	32	1
Asia	Japan, individual	30	
	Japan, in a group	7	2
Latin America (global south)	Brazil	17	
	Uruguay	4	
	Mexico	3	
	Argentina	2	
	Panama	1	
	Chile-Brasil	1	
	Guatemala	1	
	Jamaica*	1	
Africa (global south)	Kenya	1	
	South Africa	1	
	Tanzania*	1	
Austraria	Austraria	1	
Europe	Belgium	1	1
	Greece	1	
	Netherland	1	
	Czech Republic*	1	
	Norway*	2	
Asia	Philippine	3	
	Pakistan	1	
	Nepal, Group	1	1
	Turkey	1	
	South Korea*	1	
		125	5

\*=Country added after November 7 (Previous update)

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

Recognising the possible bias in the distribution of information, the fact that many of the signatories were from the Global South and Asia shows the importance of further communication with these supporters, for the implementation of the revised DoH with emphasis on the remaining challenges.

It is particularly noteworthy that on October 25, one week after the 18 October announcement of the “Helsinki Statement”, the agreement of 32 individuals belonging to the Egyptian Network of Research Ethics Committees (ENREC) was informed, on the premise that their names could be publicised, and an Arabic translation of the Statement was published on 7 November, 2024<sup>42</sup>. A note in the Arabic translation clarifies that the change from “research subject” to “research participant” did not apply to the Arabic version of the DoH. When asked about the background, the representative of the ENREC provided the following explanation:

— Since the literal Arabic translation of the word "subject" (شئ) is typically reserved for inanimate objects, we opt for a more suitable term from the outset. Consequently, we use the word "مشارك", which most accurately captures the essence of the English word "participant". (Published under the permission of the representative of ENREC)

While it is not possible to say much about this point in this report, we believe that there would be essential elements to learn through further communication with the signatories of the “Helsinki Statement”. Similarly, the term “research subject” was not appropriate in the Greek language, and the term research participant has long been established in ethical, regulatory, and legislative texts on medical research in Greece. This could be elaborated on the implications and value of the DoH.

The authors of the Helsinki Statement will continue to work together to improve the implementation of the 2024 version of the DoH. To this end, we hope that this report contributes to a common understanding of the context for future collaboration with a wider range of stakeholders.

## Conflict of interest

There is no conflict of interest related to publication of this report.

## Acknowledgment

There is no direct funding for this report. CK received travel expenses from IFAPP for her in-person participation in WMA's Regional Meeting in Tel Aviv; from the WMA for her in-person participation in WMA's Regional Meeting in Washington D.C. and waiver of registration fee for a journalist from WMA to attend the General Assembly in Helsinki.; MK joined the WMA meeting as a part of a survey of ethical issues related to the use of advanced medical technology and bioresources according to the Japan Agency for Medical Research and Development (AMED) grant (no. 24bm1523009s0801).; VB received travel expenses from IFAPP for her personal attendance at the WMA Regional Meeting in Copenhagen in 2023 and the WMA General Assembly in Helsinki in 2024, and a free registration waiver from WMA for her attendance at the WMA General Assembly in Helsinki in 2024.

The authors deeply appreciate all the collaborators, commentators who contributed to the development of this report.

---

<sup>42</sup> Together with Japanese and English versions, Arabic version is published in website and printed version of *Clin Eval*. Vol. 52 No. 3. Other language versions are welcomed.  
[http://cont.o.oo7.jp/52pop/52pop\\_contents\\_e.html](http://cont.o.oo7.jp/52pop/52pop_contents_e.html)