

## 2.5 Dr. Ramin Parsa-Parsi, German Medical Association: Workgroup Chair of the 2013 revision of the DoH

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### ① Most impressive or important changes to the DoH

Since its adoption in 1964, the Declaration of Helsinki (DOH) has been revised several times to make it more comprehensive and to respond to the changing research environment. However, the core set of ethical principles in medical research remain consistent. Hence, most of the changes made in the latest review of the DoH serve to clarify the existing provisions.

One significant development is the fact that the DoH now addresses not only physicians, but all individuals, teams and organisations involved in medical research, because the World Medical Association (WMA) considers the DoH principles fundamental to the respect for and protection of all research participants. Furthermore, by more prominently referring to healthy volunteers in clinical studies, the revised DoH recognises their significant contribution.

Another significant development is the reference to the WMA Declaration of Taipei (DoT) in paragraph 32, which provides guidance on research using health databases, big data and biobanks. This reference will increase the visibility of the DoT. The WMA will therefore have to ensure that this document, adopted in 2016, is updated accordingly.

The most important changes may, however, be the amendments to paragraphs 19 and 20 on the subject of vulnerability. These amendments, which followed long and comprehensive deliberations during three expert meetings, present a new compromise wording that will have significant impact on medical research with groups or individuals in situations of vulnerability.



Left: Dr. Ramin Parsa-Parsi at the venue just after the adoption of the 2024 DoH on October 19, at the Plenary Session of the General Assembly.

Right: Celebration message for the 60th Anniversary of the DoH, at the event space Töölön Juhlasali where the DoH was first adopted in 1964, offered by the Finnish Medical Association.

Other two messages are from Dr Kati Millimäki, the former WMA President, Finnish Medical Association, well known as one of the “three wise women” who strongly contributed to the 2000 DoH; and Kurihara, IFAPP.

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Dr. Parsa-Parsi contributed as the former working group chair of the 2013 revision of the DoH and also chaired the revisions of the other two core documents cited in the DoH: the Declaration of Geneva (2017 revision) and the International Code of Medical Ethics (2022 revision).

## **②Achievements of Munich Regional Meeting (May 2024)**

The German Medical Association (GMA) was very pleased to host one of the topical conferences in Munich as part of the ongoing revision of the WMA's DoH. The GMA teamed up with the WMA, the German National Academy of Sciences (Leopoldina), the American Medical Association, and the State Chamber of Physicians of Bavaria, to organise this meeting. Bioethics experts from around the world attended the meeting and focused their discussion on the aspect of vulnerability in order to contribute to the DoH revision process.

The conference focused on children and adolescents, pregnant people, the elderly, the incarcerated and people with disabilities. Previously, the DoH called for research to first be carried out on non-vulnerable groups; however, the strict application of the principle of subsidiarity could in fact be disadvantageous for the vulnerable groups, as they may, for example, be subject to delayed access to new therapies. The revised DoH now states that the harms of exclusion must be considered and weighed against any harms of inclusion. Of course, the protection for individuals and groups in a situation of vulnerability remains an important priority. The research must still respond to the health needs or priorities of this group. In addition, it must first be ruled out whether the research in question can be carried out on a less vulnerable group, and the group must stand to benefit from the resulting knowledge, practices or interventions.

## **③Comparing the 2013 and 2024 revisions**

Both the 2013 and the 2024 revisions of the DoH represent the culmination of a comprehensive and systematic revision process. The respective international workgroups put great effort into being as inclusive and transparent as possible. The outcome of several expert conferences on different continents contributed to the discussion processes. In addition, stakeholders from around the world had the opportunity to submit their feedback during open public consultation phases. Issues such as the use of placebos in clinical trials with human participants, informed consent and or post-trial provisions were intensely discussed during both phases. The same applied to the discussions around vulnerable groups; however, the most recent revision process had a much stronger focus on this subject. The 2013 version of the DoH first introduced a paragraph on medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories. The 2024 version, on the other, hand expanded on these provisions by referring to the WMA's Declaration of Taipei. This addition reflects the evolution of data-driven research.