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2.2 Dr. Jack Resneck, American Medical Association, Chair of the Workgroup for the revision of the DoH

Summarized from the Dr. Jack Resneck's presentations in Helsinki, considering some conversations, by Kurihara C, Matsuyama K, Baroutsou V.

①Overview of the revision

Dr. Jack Resneck, American Medical Association, who chaired the Workgroup was highly appraised during the meetings for his excellent management of the regional meetings held in various locations and the day-and-night conversations through e-mails and web meetings.

Dr. Resneck introduced various challenges raised during the regional meetings, focusing on topics to respond the changes in the society and medicine, e.g., the development of artificial intelligence (AI) and privacy protection (Tel Aviv), controversial placebo-controlled trials (Sao Paulo) and post-trial access (Vatican), emerging clinical trial designs (Copenhagen), the public health crisis (Tokyo), research in low-resource settings. The final meeting in Washington, DC, encompassed all these topics and remaining challenges and strategies for implementation of the revised DoH.

The paramount importance of the revision was the change of the term "subject" to "participant" with the promotion of meaningful community engagement regarding community members as partners of co-creation, ensuring sharing of benefits from research (Para. 6). The revision also highlighted collaborative responsibilities of non-physicians in teams and organizations (Para. 7).

Right: Conversation to celebrate the achievement, just after the adoption of the DoH at the Plenary Session of the General Assembly October 19, to the Workgroup Chair from IFAPP President.

Left: Presentation by Dr. Jack Resneck, Workgroup Chair on the successful revision of the DoH at the General Assembly October 19, 2024. Photo: ©WMA.

②Justic principle and medical ethics

Discussions of research in low-resource settings, particularly in view of global justice, included the need to recognize structural inequalities in research in risks and benefits assessment (Para. 6), and that the purpose of research is to advance individual and public health (Para. 7) maintaining the core principle that these purposes never take precedence over the rights of individual research participants (Para. 7) and that the benefit from research should be shared equally in the community.

③Protection of the vulnerable

The protection of vulnerable people was discussed at three regional meetings, with the principle of viewing vulnerability as dynamic, which had been traditionally considered fixed, and promoting their participation in research in an equitable and inclusive manner (Para. 19, 20), including women, children, and marginalised people. Whereas reforming the previous idea regarding exclusion to be the default, reflecting the regretful history, a protective sentence was also retained (last sentence in Para. 20).

④Research integrity, ethics review, and the Taipei Declaration

It is also important to note that the "research waste" should be avoided (Para. 21) and "research misconduct" must be prevented (Para. 12), ensuring scientific integrity. Research ethics committee's function was strengthened with the familiarity with local context and inclusion of a member of the general public (Para. 23). The reference to the Taipei Declaration and the statement of principles for handling large amounts of data and samples (Para. 32) are also in line with today's rapid development of AI research.

⑤Placebo use and post-trial access

The use of placebos when there is a proven intervention (Para. 33) was discussed with the Latin American community at the meeting in São Paulo involving stakeholders including CONFEMEL (Confederación Médica Latinoamericana y del Caribe, the association of medical organizations from Ibero-America and Caribe, it represents around 500,000 doctors grouped in associations). The revised texts in the motions from Uruguay Medical Association were discussed in Workgroup but through discussions reached to the final proposal. Post-trial access was strengthened by changing the term "should" to "must" with regard to making arrangement for access prior to starting clinical trials (Para. 34).

⑥Informed consent and unproven treatment

When obtaining consent from a representative for incapable person, this person's preferences and values should be respected (Para. 28, 29). Regarding the clinical use of unproven treatments, emphasis was made that this should not be a way to circumvent the protection of the participant set in the DoH (Para. 37).

During the GA, Dr. Resneck repeatedly expressed his gratitude to the members of the workgroup for accomplishing the hard task to achieve these substantial revisions.