2.4 Prof. Daniel Fu-Chang Tsai, Taiwan Medical Association; National Taiwan University

Interview: Kurihara C, Matsuyama K, Baroutsou V

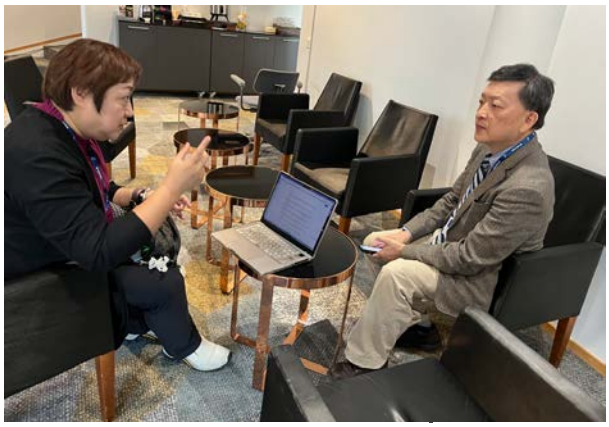
①Extensive changes, including the incorporation of the Taipei Declaration

Prof. Daniel Fu-Chang Tsai, Taiwan Medical Association, stated that the 2024 revision is extensive and includes some new concepts. The change from "research subject" to "research participant", the broadening of the scope to include non-physicians, the engagement of organizations and community, and the incorporation of the Taipei Declaration into the DoH are important changes.

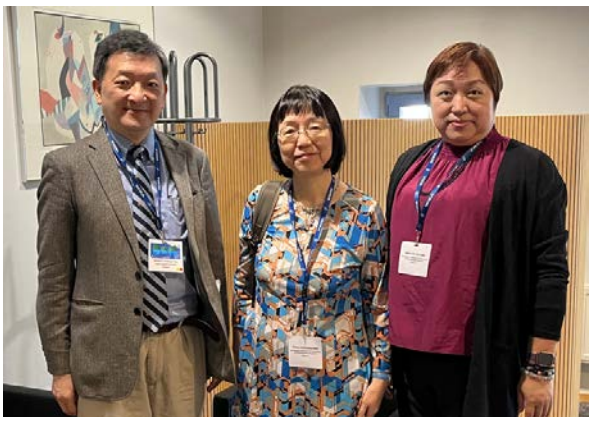
②Post-trial provision and inclusion of vulnerable people

Post-trial provision (access) is not always possible and may sometimes be a violation of laws. Physicians' obligation to provide care to patients after completion of the trial needs to be found in a way that is both ethically and legally appropriate and feasible in terms of resources.

Much has been discussed about vulnerable populations. Strengthened protection of vulnerable people has resulted in difficulties in research, which leads to inadequate evidence for better health for these people. We have moved in the direction that they should not be excluded unless there is sufficient reasoning.



Left: Prof. Daniel Fu-Chang Tsai, interviewed by Kotone Matsuyama on cutting-edge research and research review in Taiwan.



Right: Prof. Danel Fu-Chang Tsai, and interviewers: Kurihara, Matsuyama, just after the Council session October 18, 2024. As Prof. Tsai has been long engaged in the WMA's activity, his lecture in 2013 Tokyo meeting and achievement at the time of 2016 Taipei Declaration were previously reported in Clinical Evaluation in 2013 (http://cont.o.oo7.jp/41_2/p337-49eng.pdf) and in 2018 (http://cont.o.oo7.jp/46_1/p135-45.pdf).

③Taipei Declaration and Biobanks in Taiwan

Mentioning the DoT in the DoH will raise awareness about the ethical operation of biobanks and health databases. Taiwan has been struggling with strict legal regulations on biobanks. Now a consortium of biobanks has been established by the government, and researchers can apply through a single window for the use of resources from different biobanks relevant to their study purposes. Coded samples from which personal information is removed are available. Research ethics committee review at the hospitals or research institutes of research using samples from biobank is required, which evaluates not only the appropriateness of the use of the samples but also the scientific values of the research.

④Ethical review system in Taiwan including reviewing advanced technology

In Taiwan, a joint IRB system was established in 1997 but its use has been decreasing. Instead, the Collaborative IRB (CIRB) system was launched in 2013 and has been widely used to enhance review efficiency and quality. This means that one IRB conducts the primary review for multi-center research while other collaborative IRBs will conduct expedited reviews after the primary review is approved. Many institutions in Taiwan have received international accreditations from FERCAP (The Forum for Ethical Review Committees in the Asian and Western Pacific Region, WHO) and/or AAHRPP (Association for the Accreditation of Human Research Protection Programs, an international accreditation provided by a US organization). However, the review quality is standardized and monitored by the domestic accreditation system set up and operated by the Ministry of Health & Welfare of the Taiwan Government under a clear legislative framework. The review of research involving advanced technologies, e.g., regenerative medicine, stem cell therapy, gene therapy, CAR-T cell therapy, etc., is reviewed by accredited IRBs and the Taiwan FDA's review, with relevant expertise in specific scientific details. Concerning the regulation of research and application of regenerative medicine, Taiwan has learned from the experiences of the Japanese model.