

## 2.8 Prof. Dominique Sprumont, Professor of Health Law, University of Neuchatel, bridging between the CIOMS and the WMA

Interview: Kurihara C, Matsuyama K, Baroutsou V

### ①As a bridge maker

Prof. Sprumont received his PhD in 1993 on the thesis of protection of research participants in biomedical research with the support of Prof. Jay Katz and Prof. Robert Levine at Yale Law School and Yale Medical School. Returning to Switzerland he started his career as a legal advisor at the Swiss Drug Agency and drafted the 1993 regulation on clinical trials with medicinal products. Being supported by Prof. Levine he committed to the revision of the CIOMS guidelines since the 1993 revision, and subsequently for the 2000 and later revisions of the DoH, and was also involved in the drafting Taipei Declaration adopted in 2016. In all the process, he was acting as a bridge maker between stakeholders. He recently chaired the CIOMS Working Group on Good Governance Practice for Research Institutions. Kotone Matsuyama participated in this WG representing the IFAPP and the corresponding international guidelines were published in November 2023.



Left: Prof. Dominique Sprumont, at the ceremony just after the adoption of the DoH at the plenary session of the General Assembly, on October 19, 2024. He continuously attended the WMA regional meetings as a panelist, an academic adviser to the WMA, as well as bridge maker with CIOMS, as CIOMS Executive Committee member. Photo: ©WMA.

Right: With Prof. Dirceu Greco and an interviewer Chieko Kurihara, who interviewed both professors on each perspective on some controversial topics.

### ②Community engagement and Ubuntuology

The inclusion of community engagement in this revision is a major change. The Belmont Report of the United States influenced the core foundation of the Declaration of Helsinki, but there has been a major shift in the WMA approach from individualism, which primarily respects autonomy, to a more collective one. Especially at the regional conference in Johannesburg, I learned the philosophy of Ubuntuology, “We are therefore I am, I am therefore we are.” This was introduced in contrast to the Kantian principle of autonomy “I think, therefore I am”. This is also in line with the Western concept of “solidarity” and “reciprocity”, as well as in the philosophy of Confucianism in Asia, and the Japanese culture to cherish “harmony” among people in spite of their differences and particularities.

### ③Social value of research and research waste

Another important change is the statement about avoiding “research waste”. We learned from COVID-19 that the majority of research conducted during the pandemic was of limited or no social value. It is critical to evaluate the value of research not only from the view of the protection of research participants. Such paternalistic idea to overemphasize protection, which can be defined as “protectionism”, is something of the past. Beyond the fact the protection of human participants must be guaranteed in medical research, research involving human participants must also respond to the common interest.

The term “social value” was clearly stated in the CIOMS guidelines as a requirement that does not supersede respect for human rights, and that scientific validity alone is not sufficient. However, if the expression “social value” was once included in the draft revision of the DoH, it was later deleted. The official reason was that some opinions during public consultation considered the concept as vague, but some national medical associations also expressed objection that it reminded too much the idea of communism or socialism. Experiences with the concept of social values vary according to historical and personal experiences and political context. For this reason, the DoH used instead the term “advance individual and public health”, which is still consistent with the notion of social value as grounded in the 2016 CIOMS guidelines.

### ④Placebo debate

I have been involved in the placebo debate for a long time and have learned from it that it is difficult to find agreement between opposing views and that we should be careful not to spend too much time on it not to lose the opportunities to discuss other important topics. We have explained to the Workgroup that there is not a major difference of the wordings for acceptable risk of participants in placebo arm between CIOMS (minor increase above minimal risk) and the DoH (no increase of risk of serious or irreversible harm). The regional meeting in Sao Paulo addressed this issue head-on, but no one presented explicit evidence that the DoH's language has caused ethically problematic placebo-controlled trials being conducted.

In theory, the Uruguay Medical Association's argument is supported. The DoH has taken a pragmatic stance in its choice of words, which is a political science to maintain a highly influential document on the legislations worldwide and research ethics principles globally. Such topics raising conflicting views should be considered a practical decision by research ethics committees and regulatory authorities in each community, case by case basis. Art. 33 par. 2 of the DoH can not be clearer about this: “Extreme care must be taken to avoid abuse of this option.” In case of doubt, the use of placebo should be avoided.