## 2.7 Dr. Otmar Kloiber, Secretary General of the WMA

Interview: Kurihara C, Matsuyama K, Baroutsou V

### ①Important paradigm change

One important paradigm change in the revision is the replacement of the legal term "research subject" by "research participant". This is more than a matter of courtesy, but recognizes that patients play a key role in co-creation rather than being passive subjects. Patient involvement is required at all stages of research design, implementation, and result dissemination, but care should be taken to avoid manipulation of research data or results. In addition, and as advocated by the South African Medical Association in particular, community engagement in all steps of research is now promoted.

The second paradigm change lies in the aspect of vulnerability. While previously the priority was given to the exclusion of people or groups with vulnerabilities, now the question has to be asked, whether the vulnerability may be a reason to include, especially when an exclusion could aggravate the vulnerability or otherwise harm the group in question.


Above: Secretary General of the WMA organizing the Council meeting on October 18, 2024. Photo: ©WMA

Right: Secretary General discussing with IFAPP President, IFAPP Working group chair and a member just after the completion of all the program of the General Assembly on October 19.

### ②Placebo use: difference between DoH and CIOMS

Regarding the difference in wordings of acceptable risk of research participants in placebo arm when there is a proven intervention between CIOMS (minor increase above minimal risk) and the DoH (no increase of risk of serious or irreversible harm), CIOMS people explained that there is no major difference. The DoH's position is that the risks of harm, pain, discomfort or suffering which are not serious or irreversible would be assessed comparing with the value of research by the research ethics committee and then by each research participant, as there are variety of significance and duration of such detriments.

### ③Importance of governance structure articulated in the Declaration of Taipei

Referring the Declaration of Taipei (DoT) is another significant change that addresses research using identifiable data or specimen in situations where we cannot obtain explicit consent from individuals. The DoT extends the ideas of protection that have been shaped with the DoH into

the world of virtual research, where some of the traditional tools of protection can no longer be applied or may be overburdening the research. The DoT offers substitute measures by and adherence to defined governance, technical security and ethical review. As more and more research will be done with data and specimens, the reference from the DoH to the DoT is necessary.

**④Strengthened requirement for the use of unproven intervention in practice**

In the strengthened paragraph of "Unproven Interventions in Clinical Practice", the new text "*These interventions must never be undertaken to circumvent the protections for research participants set forth in this Declaration.*" was added to clarify the already existing text "*…it should subsequently be made the object of research designed to evaluate safety and efficacy*". This is in response to the misunderstanding (or the purposeful misinterpretation) that the text of the DoH allows for the serial continuation of clinical practice of unproven intervention that should be conducted as research following all requirements of the DoH. The DoH gives valuable ethical guidelines for all new medical practices and methods, however, the last paragraph focusses on the use of unproven interventions individually and compassionately in practice.