

## 2.3 Dr. Mvuyisi Mzukwa, Chairperson, South African Medical Association

Interview: Kurihara C

### ①Community engagement and vulnerability

Dr. Mvuyisi Mzukwa, Chairperson of the South African Medical Association (SAMA), regards the 2024 revision as an important milestone. The WMA's regional meetings were held in various regions and two times of public consultations were provided, that are inclusive and fair process, where a variety of views have been presented. The regional meeting in Johannesburg, South Africa, emphasized the importance of community engagement which leads to benefit sharing in the community; the new text in paragraph 6 on community engagement was mainly based on the proposal from the SAMA and extensive discussion in Johannesburg. This was presented by Dr. Edward Ngwenya during the meeting in Johannesburg.

Regarding the direction to promote research participation of vulnerable groups, it is important to respect the dignity of communities and participants, considering contextual and dynamic vulnerability. This was also important focus at the Johannesburg meeting. The process was inclusive way to listen to African voices. Promotion of engagement must be with strengthening protection.

The deletion of the word "social value" was disappointing, but many objections were understandable. Words can have different meanings depending on the social background.



Dr. Mvuyisi Mzukwa, Chairperson of the SAMA, a member of the Workgroup for the revision of the DoH at GA in Helsinki. On October 18, 2024, during the Council session.



Dr. Edward Ngwenya, a member of the Workgroup for the revision of the DoH, during the regional meeting in Johannesburg, explaining proposals from SAMA for extensive discussions on community engagement and vulnerability. On February 19, 2024, the second day of the meeting. Image captured from video.

### ②Placebo and post-trial

SAMA has sympathy with the Uruguay's position. As for the difference of the level of the risk of placebo group when there is a proven intervention between CIOMS (*minor increase above minimal risk*) and the DoH (*no increase of serious or irreversible harm*), we support the CIOMS, however, there had been explanations that there is no significant difference between these languages, thus, current wording would be a compromising position.

Provision for post-trial access "must" be arranged, and exception "must" be approved by the Research Ethics Committee. This approval must be based on understanding of the value of the community, the function of which has been strengthened. This strengthened post-trial access requirement needs to be disseminated widely.