

FEBRUARY 24-25, 2023
SAO PAULO, BRAZIL



AMA 175 YEARS



WORLD MEDICAL ASSOCIATION
**DECLARATION OF
HELSINKI**
2nd REGIONAL MEETING

Agenda (Tentative): Second Regional Meeting on the Revision of the Declaration of Helsinki (DoH)

*SAo Paulo Medical Association (APM) Hall, SAo Paulo, Brazil
24-25 February 2023*

Friday, 24 February

9:00 – 9:10 AM

Welcome

- **Dr. Cesar E. Fernandes**, President, Brazilian Medical Association
- **Dr. Carlos V. Serrano Jr.**, International Relations Director, Brazilian Medical Association

9:10 – 9:35 AM

An Introduction to the DoH

- **Dr. Otmar Kloiber**, Secretary General, WMA (TBC)
- **Dr. Jack Resneck Jr.**, President, American Medical Association

9:35 – 10:45 AM

An Overview of the DoH Principles on the Use of Placebo

- **Dr. Ramin Parsa-Parsi**, Department for International Affairs Head, German Medical Association (TBC)
- **Dr. Carla Saenz**, Regional Ethics Advisor, Pan American Health Organization

10:45 – 11:00 AM

Break (15 min)

11:00 AM – 12:00 PM

Discussion: The DoH & its Principles on the Use of Placebo

- *Participants:*
 - **Dr. Kloiber (TBC)**
 - **Dr. Parsa-Parsi (TBC)**
 - **Dr. Resneck**
 - **Dr. Saenz**

12:00 – 1:30 PM

Lunch (1h 30min)

1:30 – 3:00 PM

Discussion: Use of Placebo: Trial-design & Methodological Best Practices

3:00 – 3:15

Break (15 min)

3:15 – 4:45 **Discussion: Ethical Considerations for the Use of Placebo**

4:45 – 5:00 PM **Summary & Closing Remarks**

- Dr. Resneck
- Dr. Serrano

NETWORKING DINNER

Saturday, 25 February

9:00 – 9:05 AM **Opening Remarks**

- Dr. Resneck

9:05 – 10:45 AM **A Conversation on Regional Regulatory Perspectives on the Use of Placebo**

- *Moderator: Dr. Resneck*
- *Confirmed Keynote Speakers & Panelists:*
 - **Dr. Hilary Marston**, Chief Medical Officer, United States Food and Drug Administration

10:45 – 11:00 AM **Break (15 min)**

11:00 – 11:40 AM **Q&A: Aligning the DoH with the Council for International Organizations of Medical Sciences (CIOMS) Guidelines on the Use of Placebo and Beyond**

11:40 – 11:45 AM **Summary & Closing Remarks**
Dr. Resneck

11:45 AM – 1:45 PM **Closed Workgroup Meeting (over lunch)**

2:00 PM **City Tour**