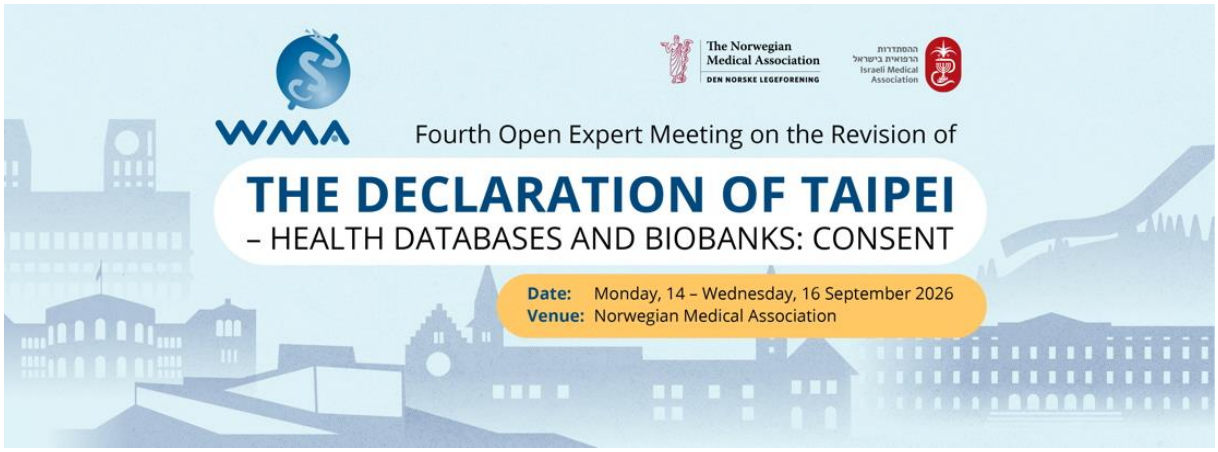


Fourth Open Expert Meeting on the Revision of the WMA Declaration of Taipei – Health Databases and Biobanks: The tension between consent, the common good and trust in public authorities

The current Declaration of Taipei requires that the collection, storage and use of data and biological material from individuals capable of giving consent must be voluntary. The basic human rights to autonomy, privacy and confidentiality entitle individuals to exercise control over the use of their personal data and biological material. At the Fourth Open Expert Meeting, the speakers will discuss approaches to ensure safeguarding ethical principles for the collection, storage and use of health data and biological material; based on informed consent and/or other safeguards.

14 September

09.00 - 09.30 Registration

09.30 -09.50 *Opening remarks*

Secretary General of the Norwegian Medical Association, Siri Skumlien

President of the World Medical Association, Jacqueline Kitulu (video)

09.50-10.10: *Introduction by WMA Secretary General, Ramin Parsa-Parsi*

A brief explanation of what the Declaration of Taipei is, including how it relates to the Declaration of Helsinki.

10.10 – 10.30 *Update from the Working Group on the Revision of the Declaration of Taipei by Christofer Lindholm, on behalf of Zion Hagay*

10.30-10.50 *Coffee break*

10.50-12.00 SESSION 1: Ethical aspects of informed consent (Part I)

Moderator: Jeff Blackmer

Speakers: Adam Berger, Dominique Sprumont, Ole-Marius Minde

In this session, the speakers will discuss different ethical aspects of informed consent. What conditions must be met for it to be considered ethically acceptable to rely on consent as a basis for the use of health data and biological material? How can one ensure that autonomy is genuinely respected and what is an "informed consent"? The session ends with a panel discussion.

12.00-13.00 Lunch

13.00-14.10 SESSION 1: Ethical aspects of informed consent (Part II)

Moderator: Jeff Blackmer

Speakers: Stefan Jovinge, Ishita Barua

14.10-14.30 *Coffee break*

14.30-15.40 SESSION 2: Safeguards in health registries (Part I)

In this session, the speakers will discuss approaches to ensure safeguarding ethical principles for the collection, storage and use of health data in health registries: based on informed consent and/or other safeguards. How do we use health data in Nordic countries and how do we justify this extensive use? How to maintain ethical safeguards beyond consent? The session will end with a panel discussion.

Moderator: Christofer Lindholm

Speakers: Heidi Beate Bentzen, Thomas Lindén, Giske Ursin

15.40- 15.55 *Coffee break*

15.55-17.05 SESSION 2: Safeguards in health registries (Part II)

Moderator: Christofer Lindholm

Speakers: Saila Koivusalo, Thorvardur Löve

Kl. 17.05-17.15

Day 1 Closing remarks - Jeff Blackmer

Kl. 19.30 - 22.00 *Dinner*

For all attendants at the Open Expert Meeting. Dinner will be held at the Norwegian Medical Association's premises.

15 September

09.00-10.05 SESSION 3: Technology and political ambitions with EHDS – the role of medical ethics

This session is intended to highlight political ambitions in the EU as demonstrated by the EHDS and other regulatory changes and discuss how medical ethics might be challenged regarding protection of patients' data, and changed preconditions and implications of consent, opt out and sharing of data for secondary and tertiary use. How do political ambitions relate to the Declaration of Taipei? Do they challenge/clash with the DoT? Do they provide inspiration for the DoT? The session will end with a Q&A.

Moderator: Leah Wapner

Speakers: Sofia Peltola, Sara Roda

Kl. 10.05-10.20 *Coffee break*

10.20-11.30 SESSION 4: When immediate crisis occurs

According to the DoT art. 16, the requirements for consent may be waived to protect the health of the population in the event of a clearly identified, serious and immediate threat where anonymous data will not suffice, the requirements for consent may be waived to protect the health of the population. In this session, the speakers will discuss what conditions must be met for it to be ethically acceptable to waive consent in an immediate crisis. The session will end with a moderated discussion with the audience.

Moderator: Jack Resneck

Speakers: Jon Snaedal, Karla Childers

11.30-11.45 – *coffee break*

11.45-12.15 - U.S. Federal Regulations and Informed Consent

Moderator: Jack Resneck

Speakers: Natalie Klein, Dr. Susan Bersoff-Matcha

12.15-12.30 *Closing remarks - Christofer Lindholm*

12.30-13.30 *Lunch/break*

13.30-17.00 ***CLOSED WORKING GROUP MEETING***