

# How to find us



## Event location

Bayerische Landesärztekammer (BLÄK)/  
State Chamber of Physicians of Bavaria  
Mühlbauerstraße 16  
81677 Munich, Germany

## Registration

Please register to participate by 17 April 2024 at:  
[www.leopoldina.org/registration-vulnerable-people/](http://www.leopoldina.org/registration-vulnerable-people/)

The Leopoldina originated in 1652 as a classical scholarly society and now has 1,600 members from almost all branches of science. In 2008, the Leopoldina was appointed as the German National Academy of Sciences and, in this capacity, was invested with two major objectives: representing the German scientific community internationally, and providing policymakers and the public with science-based advice.

The Leopoldina champions the freedom and appreciation of science. It promotes a scientifically enlightened society and the responsible application of scientific insight for the benefit of humankind and the natural world. In its interdisciplinary discourse, the Academy transcends thematic, political and cultural boundaries. It is also an advocate of human rights.



**Leopoldina**  
Nationale Akademie  
der Wissenschaften

## Research with vulnerable people

A targeted interdisciplinary discussion within the scope of the WMA Declaration of Helsinki revision

### Contact

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14 – 15 May 2024

State Chamber of Physicians of Bavaria (BLÄK)  
Mühlbauerstraße 16  
81677 Munich, Germany

In collaboration with



With kind support of



# Research with vulnerable people

## A targeted interdisciplinary discussion within the scope of the WMA Declaration of Helsinki revision

In July 2023, the German National Academy of Sciences Leopoldina established a working group focused on the Framework Conditions for Clinical Trials on Vulnerable People. The objective of the working group is to demonstrate ethically justified improvements to the framework conditions for clinical studies on vulnerable people, particularly children and adolescents.

Co-organised by the Leopoldina and the German Medical Association, in collaboration with the World Medical Association and the American Medical Association, and with kind support from the State Chamber of Physicians of Bavaria, the conference “Research with vulnerable people” represents one aspect of the working group’s approach. This targeted interdisciplinary discussion will be held within the scope of the ongoing revision of the World Medical Association’s Declaration of Helsinki (DoH). The aim of this meeting is to foster discussion on the paragraphs in the DoH focused on vulnerability with proven experts and then to proactively contribute the resulting findings to the revision process.

### Day 1 – 14 May 2024

#### 12:00 – 01:00 pm | Lunch for all participants

Chair: Jung-Yul Park, MD, Chair of Council, World Medical Association

#### 02:00 – 02:30 pm

##### Welcome remarks

Gerald Quitterer, MD, President, Bavarian State Chamber of Physicians

Lujain AlQodmani, MD, WMA President

Gerald Haug, PhD, President, Leopoldina

Klaus Reinhardt, MD, President, German Medical Association

#### 02:30 – 02:45 pm

##### Brief introduction and history of the WMA Declaration of Helsinki

Ramin Parsa-Parsi, MD, MPH, Head of Department for International Affairs, German Medical Association

#### 02:45 – 03:00 pm

##### Introduction to the current DoH revision process and recap of previous WMA conferences on vulnerable groups

Jack Resneck, MD, Chair of WMA DoH Workgroup, AMA immediate past president

#### 03:00 – 03:15 pm

##### Introduction to the current discussion in the Leopoldina workgroup

Urban Wiesing ML, MD, PhD, Chair of Leopoldina WG on vulnerable people

#### 03:15 – 03:30 pm

##### Mapping of vulnerability

Pierre Mermet-Bouvier, Senior Manager, eCOA, ICON, France

#### 03:30 – 04:00 pm | Coffee break

#### 04:00 – 05:00 pm

##### Analysis of vulnerability

Samia Hurst, Director, Institute for Ethics, History, and the Humanities, University of Geneva, Switzerland

##### Vulnerability in different research settings

Florencia Luna, Principal Researcher, FLACSO / CONICET, Argentina

##### Vulnerability as defined in the CIOMS guidelines

Rieke van der Graaf, Julius Center, Department of Global Public Health & Bioethics, UMC Utrecht, Netherlands

##### Regulatory Perspectives on Research in Vulnerable Populations

Hilary Marston, Chief Medical Officer Food & Drug Administration (FDA), US

#### 05:00 – 05:45 pm

##### Panel discussion

Panel: Drs. Mermet, Hurst, Luna, van der Graaf, Marston

Moderator: Steinunn Þórðardóttir, MD, Chair, WMA Medical Ethics Committee

#### 06:00 pm | Dinner

### Day 2 – 15 May 2024

Chair: Stefan Pfister ML, MD, Chair of Leopoldina WG on vulnerable people

#### 09:00 – 9:05 am

##### Welcome remarks

Judith Gerlach, Bavarian State Minister of Health, Care and Prevention

#### 09:05 – 10:30 am

##### Regulatory perspectives on age-inclusive research

Steffen Thirstrup, MD, PhD, Chief Medical Officer, European Medicines Agency

##### Children, subsidiarity of research

Olaf Witt, University Hospital Heidelberg, Germany

##### Conditions under which research with vulnerable groups should be permitted

Alex John London, Director, Center for Ethics and Policy, Carnegie Mellon University, US

##### Conducting research with Vulnerable Populations: Challenges and opportunities

Adam C. Berger, Director, Division of Clinical and Healthcare Research Policy, National Institutes of Health (NIH), US

##### Ethical considerations in clinical research with people with disabilities

Mohammed Ghaly, Professor of Islam and Biomedical Ethics at the Research Center for Islamic Legislation & Ethics (CILE) at the College of Islamic Studies, Qatar

#### 10:30 – 11:00 am | Coffee break

#### 11:00 am – 12:30 pm

##### Panel discussion and review of the WMA DoH paragraph on vulnerable groups

Panel: Thirstrup, Witt, London, Wiesing, Berger, Ghaly, Karla Childers, International Federation of Pharmaceutical Manufacturers and Associations

Hussain Jafri, PhD, World Patients Alliance

Steffen Thirstrup, European Medicines Agency (tbc)

Moderator: Jack Resneck, MD, Chair of WMA DoH workgroup

#### 12:30 – 01:30 pm | Lunch for all participants

### End of meeting

#### 02:00 – 04:00 pm

##### Closed WMA DoH workgroup meeting incl. selected guests

04:00 – 06:00 pm | Tour of Munich (for registered participants)

06:00 pm | Informal dinner (for registered participants)