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.

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)  
Mühlbaurstraße 16  
81677 Munich, Germany
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
12:00 – 02:00 pm | On-site registration
02:00 – 02:30 pm
Welcome remarks
Gerald Quitterer, MD, President, Bavarian State Chamber of Physicians
Lujain AlQodmani, MD, WMA President
Gerald Haug (ETHZ), 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 groups

03:15 – 03:45 pm
Mapping of vulnerability
Pierre Mermet-Bouvier
Senior Manager, eCOA, ICON, France

03:45 – 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
Hillary Marston
Chief Medical Officer Food & Drug Administration (FDA), US

05:00 – 05:45 pm
Panel discussion
Panel: Drs. Mermet, Hurst, Luna, van der Graaf
Moderator: Steinunn Þórðardóttir
MD, Chair, WMA Medical Ethics Committee

06:00 pm | Dinner

Day 2 – 15 May 2024

Chair: Stefan Pfister ML, Chair of Leopoldina WG on the framework conditions for clinical trials on vulnerable people

09:00 – 10:30 am
Delay of medicines, focus on children
Gilles Vassal
Gustave Roussy Comprehensive Cancer Center, France
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
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)