WMA Conference
on the Revision of the Declaration of Helsinki
- focused on research in resource-poor settings -

18-19 January 2024
Vatican City

Jack Resneck, Jr, MD
Immediate Past President, American Medical Association
Chair, WMA Workgroup to Revise the DoH

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The Declaration of Helsinki:
Ethical Principles for Medical Research Involving Human Participants

- One of WMA's seminal documents
- First adopted in Helsinki, Finland in June 1964
- Last revised in Fortaleza, Brazil in October 2013
- Multi-Year undertaking for current revision in 2024
  - Working group established April 2022 by WMA Council
  - Council Chair appointed 18 countries
  - Has met regularly to review feedback from regional meetings and craft proposed revisions for public comment

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First Regional Meeting Held in Tel Aviv

Strengthening language to address Technological Advancements in Big Data, Machine Learning, and Augmented Intelligence

- Current DoH language on biobanks
  - Inadequate to address consent for collection, storage, reidentification, reuse of data
  - Fails to address specific risks of AI, machine learning, big data (loss of privacy, creation of tools that cause harm)
- Alignment with Declaration of Taipei
  - Need to remedy lack of reference
  - Doesn't cover dynamic consent or risk of reidentification

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Second Regional Meeting Held in São Paulo

Ethical Considerations on Use of Placebo

- Paragraph 33: Complex subject with differing perspectives
  - When is the use of placebo, or no intervention, acceptable?
  - When is the use of an intervention less effective than the best proven one acceptable?

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Third Regional Meeting Held in Copenhagen
Emerging Trial Designs

- Adaptive/Enrichment trial designs, Master Protocols (Umbrella, Basket, and Platform Trials), Decentralized Trials, Real-world data/evidence, Challenge Trials (not really new)
  - Do we have best practices for obtaining informed consent for these types of trials?
  - Are ethics committees prepared to evaluate emerging ethical issues with them?
  - Do high-level principles of DoH already apply, or are new ones required?

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Fourth Regional Meeting in Tokyo
Research during Pandemics & Health Emergencies

- Pandemics
- Non-Pandemic Health Emergencies
- Conflict Settings
- Vaccine Challenge Trials (the COVID experience)
- Vulnerable Populations during Pandemics
- Compassionate Use

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Other Issues Arose during Prior Meetings

- Principles are fundamental and should be upheld by **all individuals** and teams involved in medical research on humans
- Replacing ***subjects*** with ***participants*** out of respect for the rights, agency, and importance of those individuals
- Need for ethics committees to have **adequate resources** and training
- Importance of **scientific rigor** to avoid research waste
- Concepts of **social value** and public health
- **Environmental impacts** of research
- Honoring **prior expressed preferences** when using legally authorized representative for consent

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Fifth Meeting: We're here at the Vatican

Research in Resource-Poor Settings

- The geography of vulnerable populations
- Experiences of diverse stakeholders in low-resource settings under the current DoH
- Post-Trial Access

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A 2-Year, Inclusive Process with Many Opportunities to Contribute

- Public Comment Period (Phase 1) beginning this month
- Johannesburg, South Africa, Feb 18-19
  - Vulnerable populations: community inclusiveness, post-trial access
- Munich, Germany, May 14-15
  - Vulnerable groups: elderly, children, pregnant, incarcerated, stigmatized, etc.
- Public Comment Period (Phase 2) in late spring
- Washington, DC, USA, August 14-16
  - Communications and final revisions

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