



Die revidierte Deklaration von Helsinki 2024

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LÄK Nordrhein, 11.2.2025



Revisionsprozess

- Seit April 2022
 - AG: Leitung AMA
 - BÄK auch Mitglied der AG
 - Warum?
 - Alle Dokumente des WMA werden nach 10 Jahren regelhaft überprüft.
 - Neue Technologien/Pandemie – neue Ethik?
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Revisionsprozess

- Konferenzen in
 - Kopenhagen, Sao Paulo, Tokyo, Johannesburg, Vatikan, München, Washington
 - Zwei mal online für Kommentare
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Revisionsprozess

- Verabschiedung: Helsinki, Oktober 2024



Foto: Urban Wiesing



Grundsätze der Revision

- Der Charakter der DvH soll erhalten bleiben.
 - Dokument von ethischen Prinzipien!
 - “readable within 15 minutes...”
 - Zahlreiche Anregungen und Einreichungen konnten nicht berücksichtigt werden!
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Neue Begriffe

- „research subject“ = „research participant“
 - „risk“ = „risk and benefit“
 - „informed consent“ = „free and informed consent“
 - erstmals „sustainability“
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Neue Ethik?

- Pandemie?
 - Big Data, KI?
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Neue Ethik?

- **Pandemien, neuer § 8:**

- “While new knowledge and interventions may be urgently needed during public health emergencies, it remains essential to uphold the ethical principles in this Declaration during such emergencies.”
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Neue Ethik?

• Sozialer Nutzen?

- DvH: weiterhin individualethisch ausgerichtet
 - 7 „The primary purpose of medical research involving human ~~subjects~~ participants is to generate knowledge to understand the causes, development and effects of diseases; ~~and~~ improve preventive, diagnostic and therapeutic interventions (~~methods, procedures and treatments~~); and ultimately to advance individual and public health.”
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Neue Ethik?

- **Placebo?**
 - Das umstrittenste Thema seit der Version 2000
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Neue Ethik?

- **Placebo, § 33:**

- “If for compelling and scientifically sound methodological reasons the use of any intervention other than the best proven one(s), the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention; and the ~~patients~~ **participants** who receive any intervention ~~less effective~~ **other** than the best proven one(s), placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.”



Wichtige Änderungen

- **Adressaten**

- 2. “While the Declaration is adopted by physicians, the **WMA holds that these principles should be upheld by all** individuals, teams, and organizations involved in medical research, as these principles are fundamental to respect for and protection of all research participants, including both patients and healthy volunteers.”
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Wichtige Änderungen

• Soziale Gerechtigkeit

- 6: “Since medical research takes place in the context of various structural inequities, researchers should carefully consider how the benefits, risks, and burdens are distributed.”
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Wichtige Änderungen

- **Probanden-/Patientenbeteiligung**
 - 6: “Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research.”
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Wichtige Änderungen

- **Ausstattungen Ethik-Kommissionen**
 - 23 “The committee must have **sufficient resources** to fulfill its duties, and its members and staff must collectively have adequate education, training, qualifications, and diversity to effectively evaluate each type of research it reviews.”
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Wichtige Änderungen

- **Unabhängigkeit und Autorität von Ethik-Kommissionen**
 - 23: „This committee must be transparent in its functioning and must have the **independence and authority to resist undue influence** from the researcher, the sponsor, or others.”
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Wichtige Änderungen

- **Multinationale Forschung**
 - 23: “When collaborative research is performed internationally, the research protocol must be approved by research ethics committees in both the sponsoring and host countries.”
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Wichtige Änderungen

- **Post study arrangements**

- 34. “In advance of a clinical trial, post-trial provisions **must** be arranged by sponsors and researchers to be provided by themselves, healthcare systems, or governments for all participants who still need an intervention identified as beneficial and reasonably safe in the trial.”
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Wichtige Änderungen

- **Qualität der Forschung**

- 12: “Scientific integrity is essential in the conduct of medical research involving human participants. Involved individuals, teams, and organizations must never engage in **research misconduct.**”
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Wichtige Änderungen

• Qualität der Forschung

- 21. “Medical research involving human participants must have a scientifically sound and rigorous design and execution that are likely to produce reliable, valid, and valuable knowledge and **avoid research waste.**”
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Wichtige Änderungen

- **Forschung mit vulnerablen Personen**
 - Bisher: strikte Subsidiarität
 - Jedoch: spätere Bereitstellung von wirksamen Medikamenten bei vulnerablen Gruppen, z.B. Kindern (ca. 6 Jahre)
 - Werden vulnerable Gruppen nicht zu viel geschützt?
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Individual, Group, and Community Vulnerability

- 19. “[...] When such individuals, groups, and communities have distinctive health needs, their exclusion from medical research can potentially perpetuate or exacerbate their disparities. **Therefore, the harms of exclusion must be considered and weighed against the harms of inclusion.**”
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Individual, Group, and Community Vulnerability

- 20. “[...] Researchers should only include those in situations of particular vulnerability when the research cannot be carried out in a less vulnerable group or community, **or when excluding them would perpetuate or exacerbate their disparities.**”
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Wichtige Änderungen

- **Daten- und Biobanken**

- Erwähnung Deklaration von Taipeh 2016
 - 32: “Where consent is impossible or impracticable to obtain, secondary research on stored data or biological material may be done only after consideration and approval of a research ethics committee.”
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Wichtige Änderungen

- **Individueller Heilversuch**

- 37: “[...] Physicians [...] must [...] avoid compromising clinical trials. These interventions [indiv. Heilversuche] must never be undertaken to circumvent the protections for research participants set forth in this Declaration.”
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Zusammenfassung

- Keine neue Ethik
 - Anwendungsprobleme der bekannten Ethik
 - Zahlreiche Detailänderungen, wording
 - Neue Komplexität und Verweis auf andere Deklaration: Daten- und Biobanken
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Zusammenfassung

• Wichtige Änderungen:

- Adressaten
 - Soziale Gerechtigkeit, Einbeziehung von Teilnehmern
 - Post-study-arrangements
 - Wiss. Anforderungen werden betont
 - Vulnerable people
 - Indiv. Heilversuch
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