LEGAL HELPDESK

Q&A NO. 4

What are the legal acts one should consider regarding research with minors?

By University of Vienna

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1. Legally binding acts

COMMENT

1. EU Regulation No. 536/2014 on clinical trials on medicinal products for human use:
   - Article 32 (Clinical trials with minors),
   - Article 10 (Special consideration of vulnerable population groups).
2. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, GDPR):
   - Article 8 (Conditions for the consent of a child with regard to information society services),
   - Article 9 (Processing of special categories of personal data),
   - Article 12(1) (Transparent information, communication and modalities for exercising the rights of the data subject).
3. Austrian Federal Law on the Protection of Natural Persons with regard to the Processing of Personal Data (Data Protection Act):
   - Section 4 Para. 4: '*When an information society service is offered directly to a child, consent to the processing of the child's personal data is lawful pursuant to Art. 6 (1)(a) GDPR if the child has reached the age of fourteen'.*
4. The United Nations Convention on the Rights of the Child (adopted 20 November 1989) (entered into force 2 September 1990) 1577 UNTS 3:
   - Article 16: Protection of privacy and honour,
   - Article 3(1): Best interests of the child ('best interest of the child' principle),
   - Article 24: Healthcare.
5. Austrian Federal Act on General Affairs pursuant to Art. 89 GDPR and the Research Organisation (Research Organisation Act).

2. Legal acts (not signed or ratified by Austria – not legally binding in Austria)

1. Council of Europe, Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (also known as the Oviedo Convention), 1999:
   - Legally binding. However, Austria has neither signed nor ratified the Convention, so it does not apply in Austria,
   - The most relevant article on this topic is Article 6 (protection of persons incapable of giving consent).
2. Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, 2005:
   - Austria has neither signed nor ratified the Convention, so it is not applicable in Austria,
   - Relevant: Article 15(1)(iv).

3. Soft law and ethical guidelines (not legally binding)

1. World Medical Association, Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, 1964 (last amended in 2013):
   - Principles 19 and 20: Vulnerable Groups and Individuals.
2. UNESCO, Universal Declaration on Bioethics and Human Rights, 2005.
3. European Medicines Agency. Committee For Medicinal Products For Human Use (CHMP) and Paediatric Committee (PDCO), Guideline on the investigation of medicinal products in the term and preterm neonate. EMEA/536810/2008, 2009:
   - Few relevant mentions. Nevertheless, recommendations on number and volume of *blood samples* on neonates.
4. Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva, 2016:
   - Guideline 17 is very comprehensive regarding informed consent (assent) from children and adolescents. This document is not legally binding.
5. Council of Europe, Recommendation CM/Rec (2016)6 of the Committee of Ministers to member States on research on biological material of human origin, 2016:
   - Article 12: Biological materials from persons not able to consent;
   - The Recommendation is only applicable to samples (and associated personal data) used for "future research purposes" (Article 2).
6. European Commission, Ethical considerations for clinical trials on medicinal products conducted with minors. Recommendations of the expert group on clinical trials for the implementation of 12 Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, 2017:
   - Recommendations on number and volume of *blood samples* for clinical trials on medicinal products conducted with minors.
7. European Fundamental Rights Agency (FRA), Consenting to medical treatment without parental consent, 2018.

Disclaimer: *this commentary aims to provide a summary of the main ethical and legal issues related to the questions put by interested stakeholders and to direct them to the relevant legal provisions that are applicable. It does not, however, preclude from reading the official sources of legislation relating to the subject matters of this document as well as those quoted by the authors and does not constitute legal advice.*