HBM4EU

science and policy for a healthy future

Ethics and health information including genetic testing

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Legislation vs ethics

Legislation

Ethics

Bounding regulations

Universally accepted. Recognized and enforced

In case of breach, may result in the punishment or penalty or sometimes both

Code of conduct

Moral philosophy guiding people about what is good or bad

Collection of fundamental concepts and principles

Health data as part of HBM study → Follow the rules and legislation for medical research

Ethical aspects coming from legislation

National legislation related to medical research varies between countries.

May be covered for example in

- Medical research act
- Acts on the rights of patients
- Biobank acts
- GDPR (EU, General Data Protection Regulation 2016/679) and national data protection acts

Medical research acts

In many EU Member States, Medical research acts are based on the Declaration of Helsinki

> *"Medical research is subject to ethical standards that* ***promote and ensure respect for all human subjects and protect their health and rights****.*
>
> *It is the duty of physicians who are involved in medical research to* ***protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects****. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent."*
>
> -WMA Declaration of Helsinki

https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Acts of rights of patients

Usually cover topics such as

- Courtesy, respect, dignity, responsiveness, and timely attention to health needs
- Adequate healthcare and continuity of care
- Receive information on own health
- Confidentiality

GDPR and definition of personal data

*"Any information related to a natural person or 'Data Subject', that can be used to **directly or indirectly identify the person** constitutes "personal data". It can be anything from a name, a photo, an email address, bank details, posts on social networking websites, medical information, or a computer IP address".*

GDPR and sensitive data

Article 9, Paragraph 1

- *"Processing of personal data revealing **racial or ethnic origin**, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of **genetic data, biometric data** for the purpose of identifying a natural person, **data concerning health** or data concerning a natural person's sex life or sexual orientation shall be prohibits"*

Except…

GDPR and sensitive data (2)

Paragraph 2

- The data subject has given explicit consent to the processing of those personal data for one or more specific purposes **(Informed consent)**
- And for fulfilling obligations of data controller e.g. legimate activities, ect.

GDPR and processing of sensitive data

Recital 51

- *”Personal data which are, by their nature, particularly sensitive in relation to fundamental rights and freedoms merit **special protection** as the context of their processing could create significant risks to the fundamental rights and freedoms.”*

Health data is always considered as a sensitive data and therefore requires specific attention for data protection.

GDRP and genetic data

According to recital 34 in the Regulation

- *"Genetic data should be defined as personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained."*

Special considerations for genetic testing

- Genetic screening are the potential implications for the family; in addition, a test result will give the individual tested no certain prediction but rather a range of possibilities that may be quite wide.
- The voluntary nature of genetic screening is of particular importance.
- Importance of confidentiality.

- Nuttfield Council of Bioethics

Ethical guidelines

- The Declaration of Helsinki, “Ethical Principles for Medical Research Involving Human Subjects”, which is considered to be the pillar of ethical standards (WMA 2018);
- The Belmont Report in 1979, “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” (NIH 1979);
- The Recommendation of the Committee of Ministers No. R(90) 3 concerning medical research on human beings (Committee of Ministers 1990);
- The Oviedo Convention on Human Rights and Biomedicine. (Oviedo 1997);
- Council of Europe in 2005: Additional Protocol to the convention on Human Rights and Biomedicine, concerning Biomedical Research (CEO 2005); and
- Council of International Organizations of Medical Sciences and WHO in 2002: International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS and WHO 2002)

Ethics – who can conduct medical research

"Medical research involving human subjects must be conducted only by ***individuals with the appropriate ethics and scientific education, training and qualifications****. Research on patients or healthy volunteers requires the* ***supervision of a competent and appropriately qualified physician or other health care professional****."*

-WMA Declaration of Helsinki

Role of ethics committee

Evaluation of the study/research plan

1. To protect the rights of the study subject
2. To ensure that ethical standards are respected
3. To ensure that legal obligations are fulfilled

Ethics Committee and ethical approval

- Ethical approval has to be applied and obtained from the Ethics Committee prior to the start of the survey.
- Processes vary between countries and sometimes even between Ethics Committees within countries.
- Process may be time-consuming and require providing additional/updated material(s) before final approval.
- Process needs to be started in early phase of study planning.

Informing a subject

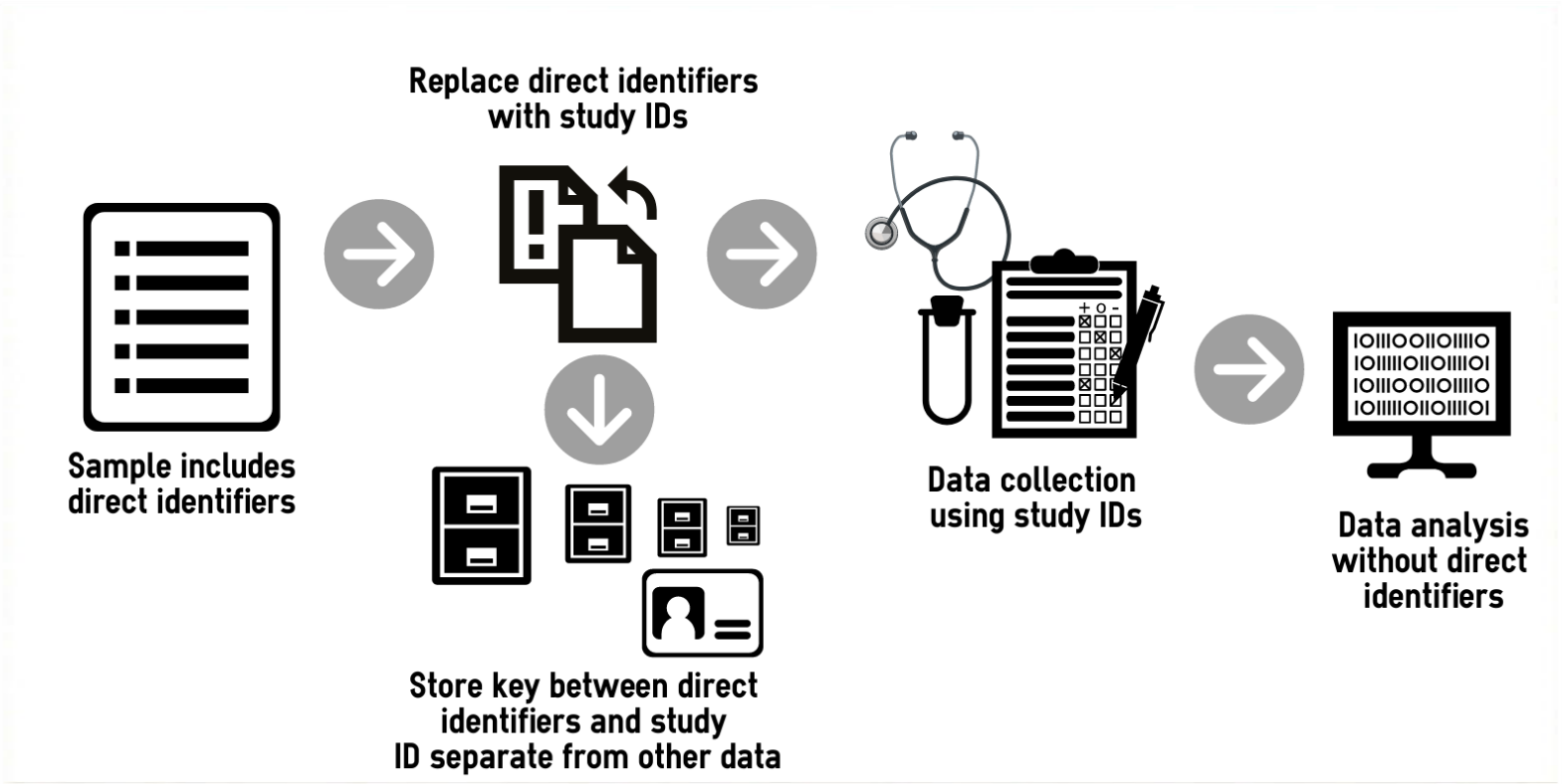
"In medical research involving human subjects capable of giving informed consent, each potential subject must be ***adequately informed*** *of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be* ***informed of the right to refuse to participate in the study or to withdraw consent to participate at any time*** *without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information."*

- WMA Declaration of Helsinki

Process for obtaining informed consent

Confidentiality

Limit the use and access to direct identifiers such as name, address, personal ID number, etc.



Individual level health data, especially genetic data cannot be anonymised, i.e. are speudonymised

More information:

HBM4EU: Deliverable 1.5 Legal and ethics policy document (coming soon) at https://www.hbm4eu.eu/deliverables/

On health specific issues also on EHES Manual, Part A. at http://urn.fi/URN:ISBN:978-952-302-700-8

Speakers's information

Hanna Tolonen, PhD, Adjunct Professor, works as Research manager at the National Institute for Health and Welfare, Finland. She received training in statistics, public health and epidemiology. In HBM4EU she is a member of the Management Board and the Ethics Board, and the leader of WP11 Linking HBM, health surveys and registers.

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