GHGA THE GERMAN HUMAN GENOME-PHENOME ARCHIVE

nfdi Nationale Forschungsdaten Infrastruktur

Research Consent

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Part I: Introduction to Consent

Why Consent Matters

The Case of Henrietta Lacks (1920-1951)

1951 Treatment at Johns Hopkins Hospital, Baltimore, Maryland; samples of cancer cells taken

1952 Establishment of HeLa cells* in research, cells are distributed, used, and commercialised without knowledge or consent

1970s Lacks' family begins to ask questions after receiving requests for blood samples

1981 Lacks' case influences the establishment of the Common Rule enforcing informed consent in research

2021 Lacks' family files a lawsuit against upwards of 100 pharmaceutical companies for 'unjust enrichment'

* HeLa cell line created by George Otto Grey is the first immortalized and successfully cloned human cell line; HeLa cells have been used in many innovations (incl. development of the polio vaccine and gene mapping)

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Why Consent Matters

Value of Research

Sharing of samples and data is essential to effective biomedical research and to understanding, diagnosing, and treating human diseases and health-related conditions.

Ethical Issues

Research with human subjects, their samples or data has the potential to infringe upon their basic rights (e.g., autonomy, privacy), to harm them, and to perpetuate systems of exploitation and exclusion.

Research requires appropriate ethical and legal governance to realise its potential benefits while resisting its potential harms.

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Why Consent Matters

1. Consent as an ethical governance measure

Consent ensures that people aren't treated as mere means to the ends of research but as participants freely contributing to planned research activities. (Consent does not eliminate the need for other governance measures, e.g., against misuse or exploitative research.)

2. Consent as a legal basis

Consent ensures that research use of personal data has a valid legal basis. Consent is one of six legal bases for processing personal data under the GDPR, Art. 6.1.a.

Consent needs to meet various conditions in order to be valid.

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Conditions for Valid Consent

‘Informed consent’ is shorthand for capacitated, unambiguous, voluntary, and informed consent.

The consent-giver must:


- have the capacity to make decisions for themselves


- unambiguously express their agreement


- give consent freely without coercion or undue influence


- be adequately informed about what it is they are consenting to


- have a sufficient understanding of what it is they are consenting to

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Challenges for Research Consent

Specific Consent

Consent is given to an individual, well-defined treatment or research action or for a specific, defined treatment or research purpose.

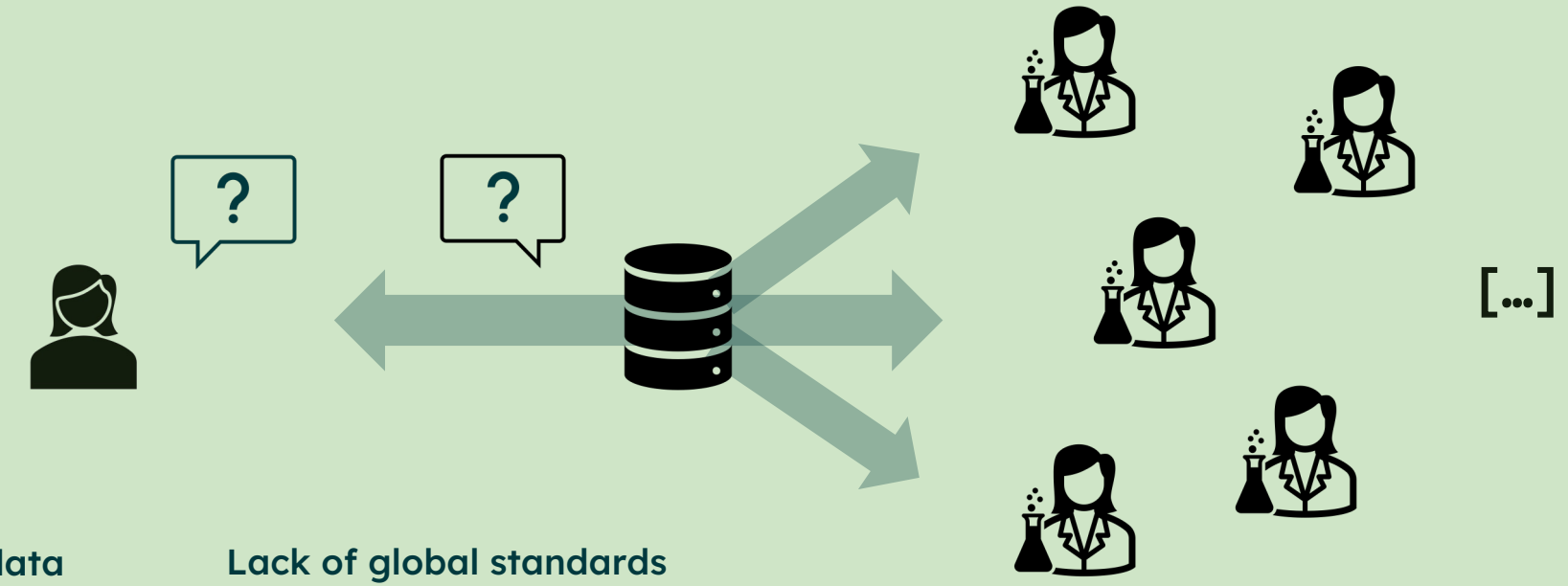
Problem: Specific consent is not suitable for research.

(*Strictly speaking, the GDPR requires consent to be specific.*)

Challenges for Research Consent

Broad Consent

Consent is given to a wide range of unspecifiable future research uses or purposes at once.



Sensitive data

Lack of global standards

How to obtain informed broad research consent?

Writing comprehensible consent forms

Technical challenges

What's Being Done

Some Go-To Resources:

Watch out for content and tools from GHGA!
https://www.ghga.de

AKEK Template Texts (in German):
https://www.akek.de/biobanken/

MII Broad Consent (depends on MII Governance):
https://www.medizininformatik-initiative.de/de/mustertext-zur-patienteneinwilligung.

B1MG Policies and Recommendation:
https://b1mg-project.eu

GA4GH Toolkits and Modules: https://www.ga4gh.org.

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MEDIZIN INFORMATIK INITIATIVE

B1MG Beyond one Million Genomes

Global Alliance for Genomics & Health
Collaborate. Innovate. Accelerate.

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Thank you for listening!