



# DYNAMIC CONSENT

EIN INNOVATIVER ANSATZ ZUR STÄRKUNG VON EINWILLIGUNG UND DATENSCHUTZ

ANJA FREI, MARY HUGGLER, DAVID SCHNEIDER UND JULIAN MAUSBACH

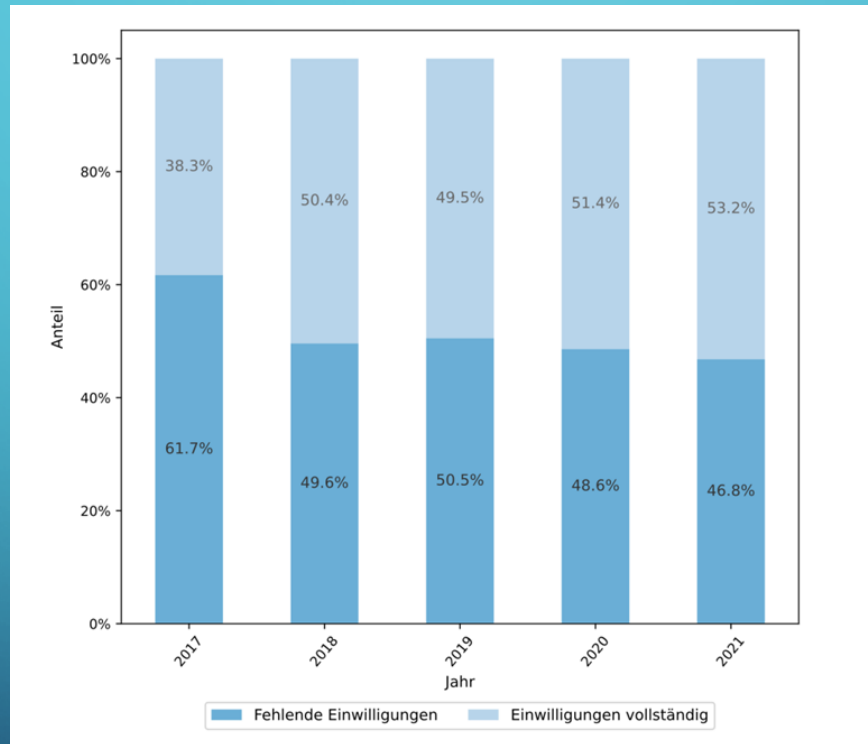
# HUMAN RESEARCH

- Human research:
  - Primary research
  - Secondary research
- Human Research Act (HRA) = Humanforschungsgesetz (HFG): "The purpose of this Act is to protect the **dignity, privacy** and **health** of human beings involved in research."
- Consent
  - Informed Consent
  - General Consent

# CONSENT: LEGAL ASPECTS

- Informed Consent as gold standard (vgl. Art. 118b Abs. 2 lit. a BV)
- Written consent in accordance with Art. 16 Abs. 1 HFG
- Exceptions by Bundesrat, for example
  - Art. 8 KlinV und
  - Art. 9 HFV
- Informed consent is project based
- For further use: general consent in accordance with Art. 32 Abs. 2 and 33 Abs. 1 HFG
- Exception: Art. 34 HFG

# CONSENT FOR SECONDARY DATA USE



Source: KOFAM,  
Statistische Berichte der Jahre 2020 und 2021  
Visualization: David Schneider



# DYNAMIC CONSENT (DC)

## Goal:

- Allow participants to remain in control of their data throughout the research process

## Core function:

- Choose detailed consent settings
- Set consent preferences dynamically

# DYNAMIC CONSENT (DC)

- Requires interactive communication between participant and researcher
- Make use of digital possibilities thanks to technological advances

--> Digital Dynamic Consent Platform

# DYNAMIC CONSENT PLATFORM

- Provision of information about research projects: recruitment, updates, results
- Interactive consent: manage consent preferences
- Personal data management
- Communication

Who can have access to my de-identified samples and information?

Not-for-profit research organisations (eg Murdoch Children's Research Institute)	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Not Sure
Universities and research institutes (eg The University of Queensland)	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Not Sure
Government (eg Australian Government Department of Health)	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Not Sure
Commercial companies (eg pharmaceutical companies)	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Not Sure

What kinds of research can they do with my de-identified samples and information?

General research use and clinical care	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Not Sure
Health/medical/biomedical research	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Not Sure
Research must be specifically related to my condition	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Not Sure
Population and ancestry research	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Not Sure

Source: Haas et al., 'CTRL': an online, Dynamic Consent and participant engagement platform working towards solving the complexities of consent in genomic research



# DYNAMIC CONSENT: COMPLIANCE WITH LEGAL REQUIREMENTS

- Right Person: Electronic signature can ensure this
- Electronic signature can be signed independently of time and place: people with reduced mobility can also participate
- Revision of ordinance law (Verordnungsrecht) in human research legislation



# WHY DO WE NEED DYNAMIC CONSENT?

- **Involvement of participants in research:** active participation strengthens autonomy
- **Data protection and privacy:** Individual control over data usage, improved data transparency
- **Building trust:** between researchers and participants
- **Digital consent management:** efficient and up-to-date

# BENEFITS FOR PARTICIPANTS

- Exercising the right to self-determination
- Controlling the use of personal health data
- Transparency about data usage
- References to further information
- Inclusion in the research process

# BENEFITS FOR RESEARCHERS

- Simplified and targeted recruitment of participants
- Simplified digital management and verification of consents
- Long-term benefit through increased trust in research and commitment of participants



# CHALLENGES

## For participants:

- Trust in data security

## For researchers:

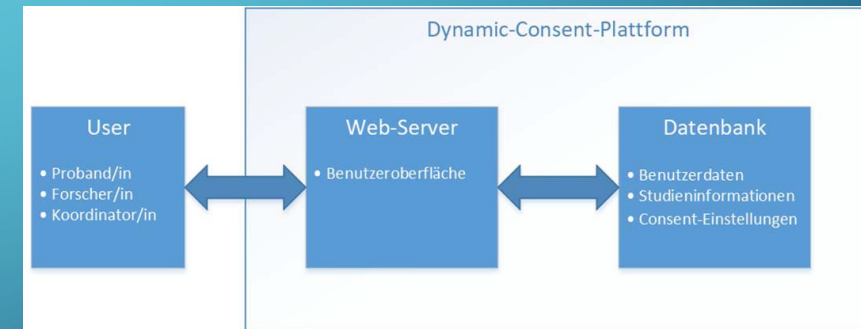
- Change of usual procedures in the research process
- Rethinking towards patient-centered research

## General:

- Financing

# TECHNICAL OVERVIEW

- Components: User interface, Server, Database
- Login: personal identification
- Permissions: User roles
- Log: data access and data mutation
- Data minimization
- Data encryption
- Blockchain



# CONCLUSION

## Dynamic Consent

- is an innovative approach to strengthening consent and data privacy
- is a communication platform for researchers and participants
- gives participants control over usage of their data
- simplifies consent management for researchers
- strengthens trust in research





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