

Secondary Research Use of Patient Data. Data Donation or Informed Consent?

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Secondary Research Use of Patient Data

Advantages

cost effectiveness, volume and breadth, readiness (e.g. electronic format)

Disadvantages

unclear or heterogeneous quality, lack of specificity

Scope

Clinical Research

- feasibility analysis
- patient recruitment

Epidemiological Research

- hypothesis generation (trends, patterns, risk factors)
- secondary research

Healthcare Research

- primary research ('real-world data')
- outcome monitoring (services, programs, policies)

Legal Framework

The EU General Data Protection Regulation

In the EU, processing of personal medical data for research purposes is forbidden unless

- (1) the data subject (i.e. the patient) has given consent to the processing, or
- (2) the processing (i.e. the research) is carried out in the public interest and under conditions laid down by EU or member state law.

Regulation (EU) 2016/679, Article 6

Schriftenreihe der TMF



U.K. Schneider

Sekundärnutzung klinischer Daten- Rechtliche Rahmenbedingungen

mit einem Beitrag von
Alexander Roßnagel und Gerrit Hornung



Medizinisch Wissenschaftliche Verlagsgesellschaft

Informed Consent

"The goal of the informed consent process is to provide sufficient information to a potential participant, in a language which is easily understood by him/her, so that he/she can make the voluntary decision regarding 'to' or 'not to' participate in the research study."

Nijhawan LP, Janodia MD, Muddukrishna BS, et al. Informed consent: Issues and challenges. J Adv Pharm Technol Res. 2013;4(3):134–140.

- specific consent, broad consent, blanket consent
- dynamic consent ("ask me each time")
- meta consent ("ask when to ask me")

Template text for patient consent forms

The challenge:

Detailed consent provided by a patient or clinical study participant plays a decisive role in determining how personal health data can be used for future research. For the consistent use of data for medical research across Germany, it is critical to ensure essential elements of patient information and consent forms are standardised. Not all future research goals are known at the time the data are captured. It is therefore necessary to describe potential future use of data for research and healthcare in very general terms when a patient/participant declares consent (broad consent). German legislation governing data protection and hospital activities varies from state to state in terms of what research can be conducted using patient-care data without explicit consent. Similarly, there is no consensus among state oversight agencies with regard to how broad consent should be worded.

Achievements to date:

All participating university hospitals have agreed on a strictly consent-based approach: while in hospital, the patient is asked to consent to future use of clinical data on the basis of clearly expressed information. They have agreed on a standardised template text for both patient information and consent. This includes identical consent options for patients, enabling data to be used consistently across sites and consortia at a later date. The template text incorporates input from recognised experts and organisations from across Germany (representatives of ethics committees, university hospital legal departments, TMF's data protection working group, and a legal advisor). The template text has been accepted by the German states' data protection agencies.

Drawbacks

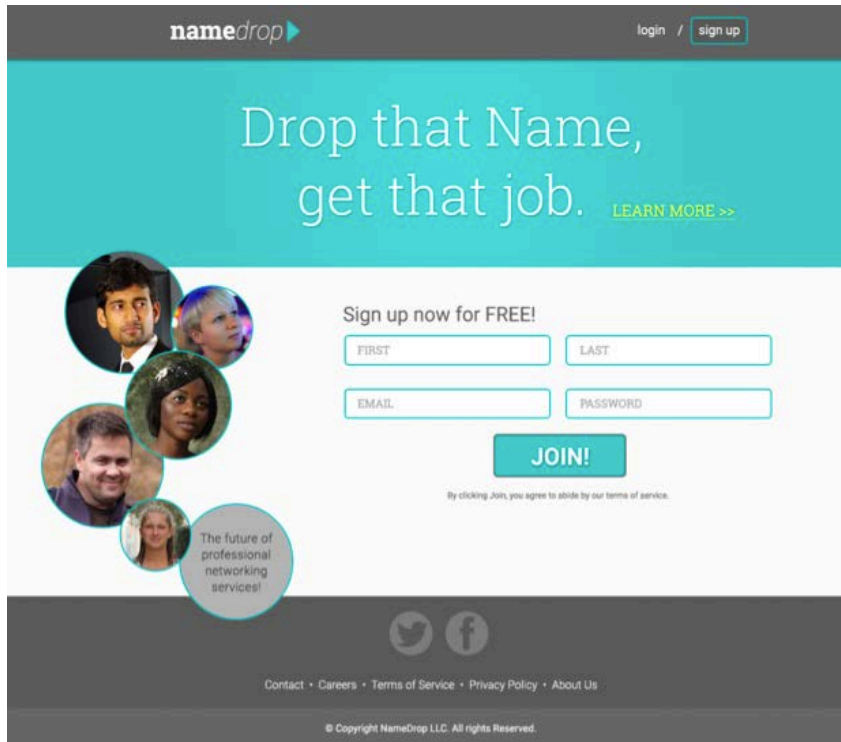
Legal Provisions

- restriction of patient autonomy
- risk of fragmented and inconsistent legislation
- unclear framework for "balancing of interests" (how? who? when?)

Informed Consent

- limited understanding by patients
- arduous implementation in clinical routine
- potential for methodological deficiencies (e.g. representativeness)

Sidekick: Adequacy, or Not, of Consent Processes



- NameDrop was a fictitious social networking site that study participants thought was real.
- All participants (US university students) agreed to terms that included demanding their first born as payment.
- The privacy policy checked off by all participants said their data would be shared with the NSA and employers.

Obar JA, Oeldorf-Hirsch A. The Biggest Lie on the Internet: Ignoring the Privacy Policies and Terms of Service Policies of Social Networking Services (June 1, 2018). TPRC 44: The 44th Research Conference on Communication, Information and Internet Policy, 2016.

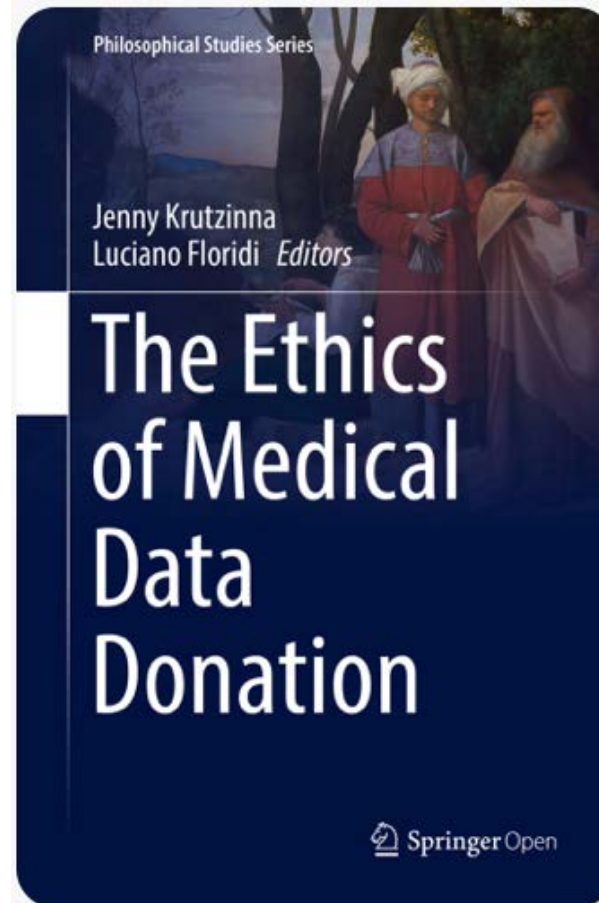
Data Donation – A Third Way?



- data donation as informed consent with less stringently limited purpose of use
- propagation of "cascade model", i.e. control options that range from one-time to case-by-case decisions on use of data

*German Ethics Council. Big Data and Health
- Data Sovereignty as Informational
Freedom, November 2019*





Krutzinna J, Floridi L (eds) The Ethics of Medical Data Donation. Philosophical Studies Series, Vol 137. Springer, Cham. 2019

Aspects of Data Donation (1)

"[Data Donation is a framework for] systematically allowing private individuals to volunteer their medical data for research purposes."

"Donations are not reciprocal, at least not in a direct and linear manner."

"Retaining individual control of the donor over data after the donation has completed would undermine the spirit of the very idea of data donation."

Prainsack B. Data Donation: How to Resist the iLeviathan.

Aspects of Data Donation (2)

"Distinguish gifting from exchanging is that the former involves a symbolic dimension that the latter lacks."

"There is a distinctive gift aspect which expresses recognition and valuation of the recipient."

Nickel PJ. The Ethics of Uncertainty for Data Subjects.

"'Donation' is from the Latin '*donum*' meaning 'gift', and a forced or presumed gift loses the spirit of being a gift."

Jones KH. Incongruities and Dilemmas in Data Donation: Juggling Our 1s and 0s.



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Legitimate Data Donor Expectations

- willingness to donate must not be exploited by recipient or third parties
- donation must be handled responsibly and put to work effectively
- no third-party interests must interfere with the equitable distribution of the donation
- appropriate safeguards must be implemented
- burdens arising from donation must be minimized

Jones KH. Incongruities and Dilemmas in Data Donation: Juggling Our 1s and 0s.

Conclusions

"Data Donation", when defined as

the voluntary, non-reciprocal process of allowing third parties to use own personal data for research purposes under the conditions attached to the donation,

may help to

reduce (or even avoid) restrictions of patient autonomy while simplifying practical implementation (e.g. via opt-out mechanisms).

Thank you for your interest!