Research Project

Ethical and legal regulation of Big Data research – towards a sensible and efficient use of electronic health records and social media data

Third-party funded project

Project title Ethical and legal regulation of Big Data research – towards a sensible and efficient use of electronic health records and social media data

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Organisation / Research unit

Departement Rechtswissenschaften / Assistenzprofessur Gesundheits- und Spitalrecht (Seitz)

Ethik / Bio- und Medizinethik (Elger)

Department

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Big Data research using electronic health records (EHR) and social media (SM) available through the internet are an effective and constantly improving means to generate quick and valuable knowledge about the functioning of human beings and society. They aid to answer important research questions related to health, well-being, functioning and behaviour of various populations and institutions. This type of readily available data is valuable for many disciplines including medicine, psychology, and sociology. It holds the potential to have a direct impact on quality and cost-efficiency of health care as validated by real time use of Big Data in smarter healthcare and cities projects.

As research regulations have been originally conceived for clinical trials, researchers carrying out studies that use EHR and SM face considerable uncertainty. Recently, the public has reacted strongly to the perception that research involving data and biological samples (generating genetic data) is underregulated and therefore data abuse is becoming a high risk. Big Data research has opened previously unprecedented possibilities of data research and has increasingly highlighted public fears of abuse: predictive analysis of EHR is being developed for so-called smarter hospitals to help identify in real time patients at high risk for health deterrioration. Models based on algorithms are developed to predict and address healthcare and resource allocation in smarter hospitals. In medicine and psychology, routine data from EHR offer the potential to use data from millions of people to answer important research questions at much lower cost than clinical trials. Combination of information from SM, consumer data (e.g. data from the Migros Cumulus card) and EHR data could enable in finding objectivable results that were previously only available through more costly subjective tools such as patient or consumer questionnaires.

This type of very promising Big Data research raises new technical and regulatory concerns due to its specific characteristics: the vast amount (variety, volume) of useful data generated at an unprecedented speed (velocity) encompassing not only medical information but also sociodemographic and financial data. It thus presents challenges

on veracity at various levels of data flow, ranging from the extraction of information to data sharing and methods of data management and analysis. Among the most pressing ethical and regulatory concerns are issues of consent, privacy, confidentiality and conflicts of interest. Countries are struggeling individually and often differently with the regulatory void, and the varying domestic approaches lead to concerning barriers for international research. In Switzerland, it is at present not always clear which type of Big Data research is considered human subject research and must receive approval from cantonal research ethics committees (CRECs). Furthermore, CRECs lack capacities to treat all research from such grey zones, especially if they are done outside of medical faculties. Some researchers have sought to address this shortcoming by enacting their own department or faculty commissions to approve research. These commissions, in contrast to the CRECs, do not have a legal status and their competence and scope remain undefined.

The past has shown that if research remains largely unregulated there is a risk of public "backfire". Citizens' fear of abuse and of research taking place "behind their backs" can create the feeling that regulations must be particularly strict. There are several recent historical examples to this effect. The present project fills the existing research gap of how to deal ethically with dsata while at the same time avoiding unnecessary barriers to otherwise beneficial Big Data research. Guidance for ethics committees worldwide, and also locally in Switzerland, is urgently needed. The objectives and methods of this project are the following:

i.Review existing national and international ethical as well as legal guidance related to Big Data research involving EHR and SM using classical comparative analysis methods.

ii.Understand the attitudes and local needs of researchers and barriers they fear: to this aim we will carry out qualitative interviews with (a) researchers and (b) with those whose data are used.

iii.Use the results from the preceding parts (i. & ii.) and perform thourough ethical analysis, after review of the relevant ethico-legal literature, to influence the local and international regulatory and ethical debate and to propose and further a sensitive and efficient research ethics framework.

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Follow-up project of 1002419 Agequake in prisons: Reality, policies and practical solutions concerning custody and health care for ageing prisoners in Switzerland

Add publication

Published results

4498981, Favaretto, Maddalena; De Clercq, Eva; Elger, Bernice Simone, Big Data and discrimination: perils, promises and solutions. A systematic review, 2196-1115, Journal of Big Data, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

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Add documents

Specify cooperation partners

ID	Kreditinhaber	Kooperationspartner	Institution	Laufzeit - von	Laufzeit - bis
4238545	Elger, Bernice Simone	Burton-Jeangros, Claudine, Prof. Dr.	Département de Sociologie, Université de Genève	01.02.2017	31.01.2021
4238553	Elger, Bernice Simone	Papaux van Delden, Marie-Laure, Professor	Département de droit civil, Université de Genève	01.02.2017	31.01.2021
4487243	Elger, Bernice Simone	Briel, Matthias, Professor	Institute for Clinical Epidemiology and Biostatistics, Universitätsspital Basel	01.02.2017	31.01.2021
4528247	Elger, Bernice Simone	Egli, Philipp	-	01.01.2019	01.01.2023

ID	Kreditinhaber	Kooperationspartner	Institution	Laufzeit - von	Laufzeit - bis
4528248	Elger, Bernice Simone	Gaab, Jens, Prof. Dr.	Fakultät für Psychologie, Universität Basel	01.10.2022	30.06.2027
4528249	Elger, Bernice Simone	Rothstein, Mark, Prof. Dr.	Institute for Bioethics, Health Policy and Law, University of Louisville	01.01.2014	01.01.2021

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