Winter School for ECRs on ethics in data-rich medicine

New ethical challenges in data-rich biomedical research:
a country comparison of consent in UK, Austria and Germany

Date:	**October 16-20, 2019**
Call for papers - Deadline:	**April 23, 2019**
Venue:	**Munich**

Organisers:

Prof. Dr. med. Alena Buyx, Gesine Richter MA, MBA

Institute for History and Ethics in Medicine, Technical University Munich, Ismaninger Str. 22, 81675 München, Germany

The Winter School

In May 2018, the European Data Protection Regulation (DSGVO, EU Regulation 2016/679) came into force. Despite the overall objective of European harmonization, the GDPR gives member states leeway in determining whether patient consent is required for secondary data use in medical research, and in which form. These differences in legislation have various practical and normative consequences, most of which have not yet been fully analysed.

During the **Winter School**, the ethical, legal and social challenges of consenting to the complex primary and secondary use of ever larger data sets for biomedical research will be discussed in an interdisciplinary setting. Debates will focus on comparing current and planned forms of consent in light of novel regulation in Germany, Austria and a soon-to be non-European country, the UK.

The use of massive data sets and increasingly sophisticated data analysis methods, including machine learning and autonomous algorithms, comes with numerous regulatory, ethical and social dimensions. Three major trends are shaping current data-rich medicine: 1) the increasing diversity of data and emerging options of their decontextualization and recontextualisation in and for medical research; 2) the growing acceptance of broad or even blanket consent for data-rich research projects; and 3) the internationally differing implementation of the GDPR with regard to the use of secondary data, with and particularly without consent.

In view of international research collaboration, comparing new national approaches to implement the research exemption in the DSGVO is essential. Germany, e.g., now allows data processing for scientific or historical research purposes or for statistical purposes, at least prima facie, without a declaration of consent. It is entirely unclear how this new legal provision has penetrated research practice, however. A comparison with countries that are more restrictive, or that have long-term experience with more permissive approaches, such as broad or blank consent (Austria, UK) should help to anticipate the implications of the novel practice. During the Winter School, the arguments for and against new practices and regulations in data-rich biomedical research will be analysed and sharpened, with a view to enable young researchers to contribute recommendations for ethically and socially acceptable biomedical data governance and policy in their respective countries.

Our research questions

Current developments lead to tensions between protecting participants' privacy and right of self-determination, exploiting the undoubtedly great scientific and social potential of big data, and responding fairly to current challenges through policy and regulation.

Important research questions from biomedical ethics and related fields are, e.g.:

- What are the ethical responsibilities of data controllers and their institutions in handling increasingly diverse data in research, in light of novel regulation?
- What competences and responsibilities should patients have with regard to their own data and how can these be achieved?
- Which ethical and social demands on the information and consent process for data use should / can be effectively implemented in an age of increasing data delimitation, and what are the implications of the new regulatory provisions in this respect?
- Should the ideal of informed self-determination in data-rich medicine be kept and, if so, how?
- How can knowledge transfer and communication to data-rich medicine be optimized? Etcs.

Our Programm

The **Winter School** will offer early career researchers (ERCs) in biomedical ethics and related fields from Germany, Austria and Great Britain the opportunity to develop their ideas and network with each other as well as with experts in the field. It will take place in the heart of Munich and involve a rich academic programme, site visits to relevant research institutions as well as opportunities for social and cultural exchange.

National and international experts in the fields of medical ethics, molecular biology, philosophy, social sciences, European and health law, data protection and policymaking will stimulate transdisciplinary discourse and offer feedback on ERC presentations.

Your Participation

Participants are invited to contribute to the following areas - country-specific views are welcome:

- Novel ethical challenges in the international context of data use in research
- Novel legal challenges in the international context of data use in research
- Novel forms of consent in data-rich medical research
- The social and communicative dimension of data-rich research

The number of participants is limited to 15. Conference language is English. Costs for travel and accommodation will be covered. In addition, all participants will receive a stipend (€ 300) conditional upon delivery of a manuscript suitable for publication in the planned anthology/special issue.

ERCs from Germany, Austria and the UK are invited to submit an abstract in English (max 500 words) as well as a short academic CV exclusively in electronic form (PDF) by e-mail until **April 23, 2019** to adina.von-malm@tum.de (**re: Winter School/Klausurwoche**)