Towards a European legal framework for data protection –
Implications for scientific research of the draft EU Data Protection Regulation

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BACKGROUND - SUMMARY
Accurate data is vital to enlightened research and policymaking, particularly publicly available data that are redacted to protect the identity of individuals. Privacy is vital when it comes to health and biomedical research. Until now our health records have been pretty well protected, mostly by inefficiency. With electronic medical records and the widely shared health data that Utopia requires we can’t put our trust in inefficiency any longer. The implementation of a 1995 directive of the European Union (95/46/EC), has created a scattered array of differing national legislations within Europe. Some countries even have different regional laws on data protection, making it even harder for cross-border data transfer for research. A first proposal for Data Protection Regulation was published by the EU Commission in January 2012.

Ensuring data protection across Europe

Key changes of the EU Data Protection Regulation Proposal 2012/0011 (COD):

• A right to be forgotten (not about erasing past events)
• Easier access to your own data
• When consent is required you must be asked to give it explicitly
• More transparency about how your data is handled – easy to understand
• Being informed about data losses
• Increased responsibility and accountability
• Exemptions for research – Art. 83 Processing of personal data concerning health which is necessary for historical, statistical or scientific research
• Definition of health data:
  purposes of preventive or occupational medicine, medical diagnosis, the provision of care or treatment of the management of health-care services, reasons of public interest in the area of public health, other reasons of public interest in areas such as social protection purposes, such as patient registries

Infobox TMF (more: www.tmf-ev.de)

TMF - Technology, Methods, and Infrastructure for Networked Medical Research e. V. – is an umbrella organization for medical research networks in Germany. As of October 2011, 89 mostly academic medical research networks and institutes across the country are members of TMF. The TMF was founded as a non-profit organization in 1999 and is funded by the Ministries of Education and Research (BMBF), of Health (BMG), of Economics and Technology (BMWi), and the German Research Council (DFG). The TMF aims at improving the organization and infrastructure for networked medical research, i.e. clinical, epidemiological and translational research.

Main Expertise at TMF

• Legal and ethical framework conditions
• Quality management & controlling
• Interconnection of research and health care
• Standards and terminology
• IT infrastructure for clinical research

Philosophy at TMF

• Bottom-up approaches & consensus-driven
• Address scientist-defined needs
• Develop generic solutions

TMF working groups (WG)

• WG Biobanking
• WG IT infrastructure and quality management
• WG Data protection, privacy and security
• WG Management of clinical trials
• WG Medical technology
• WG Molecular medicine
• WG Zoonosis and infection research
• WG Forum grid
• WG Patients representatives forum develop:
  - expert & legal opinions - consulting -
  - eServices - IT infrastructure & tools etc.
  available for free!

TMF book & publication series

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Data protection
Informed consent
Biobanking regulations
Biospecimen quality

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