Fine-grained data protection and security frameworks for sharing health data in medical research

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One of the major factors in research involving patient data is its availability and legality of its use. The question becomes even more pertinent as more and more scandals with use of patient data unravel. Whether EHR data or other patient data collections can be re-used for research and how to avoid critical mistakes in that regard is one of the major issues research teams are faced with.

The *Institut für Rechtsinformatik* (IRI), part of the Law School of Leibniz Universität Hannover, specialises in answering such questions, for example as the legal partner in European-wide research projects. As such, IRI plays a unique role compared to the other partners in the research groups. IRI focuses on supporting the researchers through providing an ethically and legally compliant framework for sharing medical data and answering any legal questions stemming thereof. The framework stands as a precondition of data sharing and allows the other partners the confidence that their research is both legally compliant, and (thanks to close cooperation with security specialists) state of the art secure.

During the past years, IRI (next to other research endeavours beyond the medical projects) has participated in a number of ICT for health projects (co-)funded by the European Commission. Some on-going projects are *p-medicine*, *EURECA*, *CHIC*, *Linked2afety* and *MyHealthAvatar* http://www.iri.uni-hannover.de/current-research.html). Examples of successfully completed projects are *ACGT*, IRI's first ICT project, and *PONTE*.

While the research teams in them focus on achieving different results, IRI's role remains the same – guaranteeing compliance with the legal requirements based on the legal research performed within the project. To fulfil that aim a highly flexible legal framework once developed in *ACGT* is being re-evaluated and adapted to the needs of the particular project – fitting the variety of projects needs and uses.

For example, in *EURECA* – a project concerned with bridging the gap between research and care data - a focus is put on Natural Language Processing and semantic interoperability. Huge amounts of patient data are needed initially for the development of envisaged IT tools. Thus a "Network of Trust" for secure data sharing and use has been built up for the project duration, which establishes "de-facto anonymity" of the concerned patient data via de-identification and security measures as well as contractual obligations for partners having access to the data. Beyond the project lifetime it is the outcome, for example the Semantic Interoperability Layer, that will be equipped with the necessary legal preconditions for its use.

The project *p-medicine* which is aiming at developing an IT infrastructure and VPH models to accelerate personalized medicine in cancer therapy relies on a similar data protection and security framework, but provides a special feature that allows back-coupling to the patient when a treatment has been found that could be of benefit for him (if the patient has given his consent). *p-medicine* will also establish a meta biobank (p-BioSPRE), an IT tool which enables biobanks to provide information on their samples and data to the research community which can use the convenient search engine function in full compliance with the applicable legal and ethical rules in order to protect the donors' privacy.

Linked2Safety - designed to reinforce the exchange of health related data among research institutions and to enhance the cross-border secondary use of such data - has introduced the "data cubes" approach. Data is rendered anonymous by deletion of identifiable parameters, by accumulation and by the introduction of turbulences in the parameters that make it impossible to recalculate the original value before made available to researchers.

During our presentation we would be happy to provide interested participants with an overview of the legal framework(s) IRI uses to secure the legal and ethical standards within the projects it participates and accompany this with an introduction to the main legal problems in the domain.