



Personal Data Protection - GDPR

Mr. Jeroen Knijpenga LL.M. MCIArb

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- What is personal data : health data
- Principles of protection
- What constitutes good protection : data leaks
- Using and Sharing data : research
- Countries vs EU vs US – Globe
- Take home messages



Most remarkable

- New European law : General Data Protection Regulation (GDPR)
- Registries are endorsed
- Further processing – research exemption
- Data minimisation
- Processing based on consent – non-advisable

What is personal data

- Name, address, date of birth, employment data, etc.
- Special categories include:
 - racial or ethnic origin;
 - genetic data;
 - biometric data for the purpose of uniquely identifying a natural person;
 - data concerning health; or
 - data concerning a natural person's sex life or sexual orientation.
- Example 1: ID number : personal or anonymized data : Identifiable
- Example 2: Photograph : normal or special category

Principles of protection

- EU Digital Single Market, boost digital innovation
- Human right, article 8 European Convention on Human Right (EHRM)
 - Everyone has the right to respect for his private [...] life [...].
- Processing of data include:
 - collection, recording, storage, adaptation, retrieval, consultation, dissemination, combination, destruction, etcetera.
- Special Categories: Processing of personal data [...] shall be prohibited
- 10 exceptions, controller ensures compliance
- Controller is in control, processor follows controller

What constitutes good protection

- Technical measures
- Organisational measures
 - Data minimisation;
 - Limited storage period;
 - Protocols on local storage (USB / Laptop);
 - And more: ask your data protection officer.
- Personal data breach (hack, lost USB stick or laptop)
 - Notifying authorities (NL 2016: 5500 notifications);
 - Notifying patients under certain circumstances;
 - Media coverage.



Using and sharing data : research

- Permission – not advised, can be withdrawn
- By law, for health sector, from the 10 exceptions for special category:
 - preventive or occupational medicine;
 - public interest in the area of public health (incl. clinical trials);
 - scientific purposes.
- Research exemption:
 - Further processing
 - Rightfully collected personal data;
 - Compatible purpose of original collecting;
 - Legal basis for providing data to EBMT Registry.

- Research exemption features:
 - Data subject's consent not needed;
 - Limited obligation to inform data subject;
 - Consistency of dataset ensured :
 - Data subject not entitled to erasure of the data,
 - Data subject's right to object against processing overridden;
 - Appropriate safeguards needed (article 89 GDPR):
 - technical measures, pseudonymisation is recommended,
 - organisational measures, in particular the principle of data minimisation.

- Broad interpretation
 - (159) [...] For the purposes of this Regulation, the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research.
- Consent for Clinical trials, but data processed is part of Regulation
 - (161) For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council (1) should apply

- Inform the patient
 - (62) [...] it is not necessary to impose the obligation to provide information where the data subject already possesses the information [...] or where the provision of information to the data subject proves to be impossible or would involve a disproportionate effort. The latter could in particular be the case where processing is carried out for [...] scientific [...] research purposes [...]. In that regard, the number of data subjects, the age of the data and any appropriate safeguards adopted should be taken into consideration.
- Keep data after usage
 - (65) [...] the further retention of the personal data should be lawful where it is necessary, for [...] scientific [...] purposes [...].

- Registries
 - (157) By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions [...]. [...] Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people [...]. In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards [...].
- Again: safeguards (art. 89 GDPR): “for the rights and freedoms of the data subject [...]” technical and organizational “in particular in order to ensure respect for the principle of data minimisation”.



Countries vs EU vs US – Globe

- Countries : health data, research exemption, authorities collaborate
- EU : General Data Protection Regulation (GDPR) as of 28 May 2018;
- US : Before ‘Safe Harbour’, now ‘Privacy shield’ – likely not future proof;
- US and Other countries : Concluding EU model clauses advisable



Take home messages

- GDPR as of May 2018;
- Research Exemption, most important:
 - Original collection is done rightfully;
 - Compatible purpose
 - Data minimization
 - Safeguards, technical and organisational
- Connect to the Data Protection Officer of your organisation!



Thank you!

j.knijpenga@legallinq.com