



Medical Benefits, Ethical Considerations and Judicial Rules

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Register-based Research

- Research using information in registers at governmental institutions or other organisations and where the information can be traced to an individual
- Usually low risks and non-interventional because the information is often already stored in databases
- But, can be "active" research where new information is gathered and compiled, i.e. in longitudinal research projects



Acts and Regulations

- Helsinki Declaration
- Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
 - Etikprövningslagen
 - Personuppgiftslagen (PUL)
 - Biobankslagen
 - Offentlighets- och sekretesslagen
 - Patientdatalagen
 - Lagen om hälsodataregister
 - Arkivlagen



Regulation (EU) 2016/679

The processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be subject to appropriate safeguards for the rights and freedoms of the data subject pursuant to this Regulation.

The further processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which do not permit or no longer permit the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data).

Individuals rights to rectification, to erasure, to be forgotten, to restriction of processing, to data portability, and to object when processing personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.



§ 33

It is often **not possible to fully identify the purpose** of personal data processing for scientific research purposes at the time of data collection.

Therefore, data subjects should be allowed to give their **consent to certain areas of scientific research** when in keeping with recognised ethical standards for scientific research.

Data subjects should have the **opportunity to give their consent only to certain areas of research** or parts of research projects to the extent allowed by the intended purpose.



§ 157

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 and improve the efficiency of social services. **In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law.**

§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. Scientific research purposes should also include studies conducted in the public interest in the area of public health.

§ 160

Where personal data are processed for historical research purposes, this Regulation should also apply to that processing. This should also include historical research and research for **genealogical purposes**, bearing in mind that this Regulation **should not apply to deceased persons**



Article 5

(b) Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes (**‘purpose limitation’**)

(e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data **may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes** subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject (**‘storage limitation’**)



Article 89

Safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes

1. Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to **appropriate safeguards**, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of **data minimisation**. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner.



- **Research, statistical purposes and archiving**
- **Ensure safeguarding of data**
- **Data minimisation**
- **Stored for longer periods**
- **Slightly wider definition of research purpose/project**
- **Informed consent**
- **Rights to rectification and/or to be "erased"**



Ju 2016:04 Data Protection Inquiry

- Additional Swedish legislations and regulations
- Sanctions
- Sensitive personal information

Inga-Lill Askersjö (Justice of the Supreme Administrative Court)
Maria Jonsson and Ulrika Söderqvist

Final conclusions 12 May 2017



U 2016:04 Inquiry on Personal Information in Research

- Analyze further regulations needed for research using personal information
- Analyze needs for changes in the Ethical Approval Act (2003:460)
- Analyze the need for adjustments in the law on research about hereditary and environmental conditions on health – "Life Gene Act" - (2013:794) and the Act on registers in forensic psychiatry (1999:353)
- Regulations on research databases

Cecilia Magnusson Sjöberg (Professor of Law, Director of the Law & Informatics Research Unit at Stockholm University)

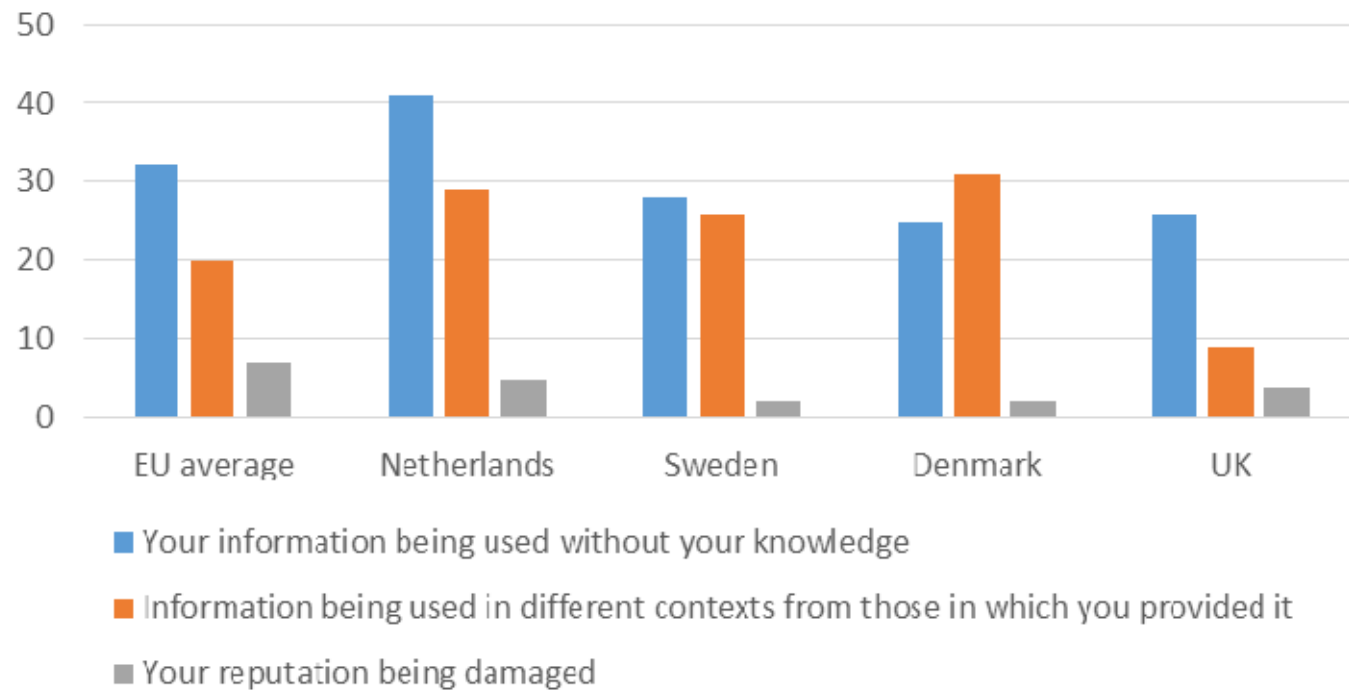
Staffan Malmgren, Magnus Stenbeck och Linda Stridsberg

Partial conclusions 1 June 2017

Final conclusions 8 December 2017.

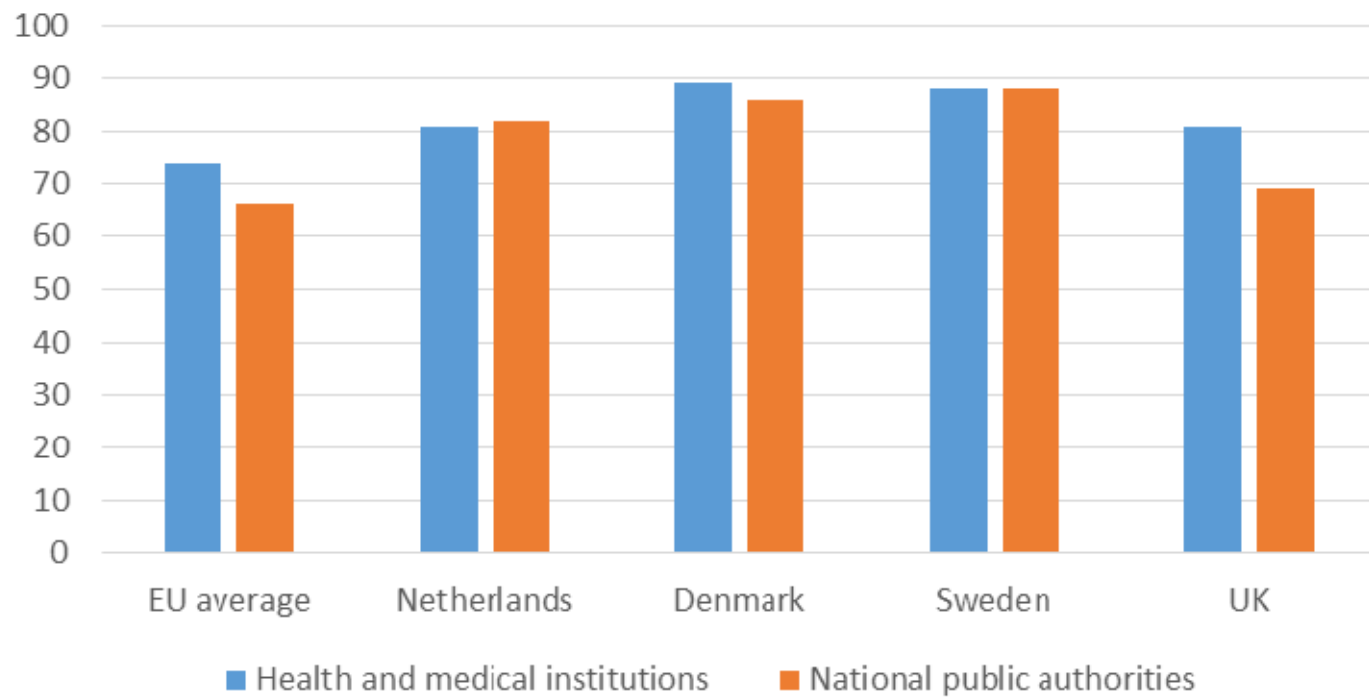


Potential risks for your personal information





Trust to protect your personal information





Explicit approval required

