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REGISTER BASED RESEARCH AND THE EUROPEAN DATA PROTECTION REFORM

What was the purpose of the reform?

- *Goals*
 - to reduce European heterogeneity
 - provide same individual protection across borders
 - facilitate cross-border movement of data
 - Strengthen individual control over personal data across and outside the European community
- *What is homogeneity?*
 - same rules in all subject matter areas
 - same rules in all member states
- *Positions on the homogeneity goal*
 - KOM and the parliament were strongly in favor
 - The Council wanted member state influence

And what was the threat?

- The proposed extensive strengthening of individual rights to delete or conceal data from the public eye and from official records
 - Threatened the constitutional principles of public disclosure
 - Threatened the principles of accountability through archiving
 - Hence, questions on the risks of legalizing censorship emerged
 - Threatened the set up of population registers for statistics and "welfare state management" purposes
 - Threatened academic and other research using individual data, e.g. in order to develop prevention and treatment

Specific problems for research

- Informed consent
 - Ethical vetting
 - The purpose limitation principle
 - "The right to be forgotten"
 - Special rules on health data
 - Pseudonymisation
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- *On all these issues, we arrived at common sense solutions providing exemptions and/or possibilities to decide on national interpretations that will work for our research communities.*



Saving lives while maintaining integrity

October 20th, 13.00–15.00



**Karolinska
Institutet**

Room JAN 4Q2, European Parliament

How modern register-based research is carried out and how to best regulate data protection. Lunch seminar hosted by MEP:s Cecilia Wikström and Jytte Guteland, co-sponsored by the Karolinska Institutet and Stockholm County Council, Sweden.

From 13.00 Light lunch served

13.15–13.45 The importance of registers for scientific and medical research

Welcome by MEP *Cecilia Wikström*. Professor *Anders Hamsten*, Vice-Chancellor of Karolinska Institutet on the importance of register-based research.

Video presentations by Professor *Hans-Olov Adami*, former Chair, department of Epidemiology, Harvard T.H. Chan School of Public Health and Professor *Juleen Zierath*, Karolinska Institutet, Chairman of the Nobel committee on the role of register-based research for research progress.

13.45–14.15 Modern register-based research: how is it carried out and applied?

Professor *Olof Nyrén*, Karolinska Institutet. Professor *Camilla Stoltenberg*, Director General, Norwegian Institute of Public Health. Dr. *Svetlana Bajalica Lagercrantz*, Senior Consultant in Oncology and Clinical Genetics, Associate Professor at the Karolinska Institutet, and breast cancer patient.

14.15–15.00 Questions, discussion and final remarks.

Dr. *Magnus Stenbeck*, Associate Professor at Karolinska Institutet. Summary by Professor *Anders Hamsten*. Final remarks by MEP *Jytte Guteland*.

Moderator: Mr. *Håkan Jonsson*, former State Secretary for European Affairs, Sweden

Mandatory registration by e-mail to sandra.runsten@halvarsson.se. Welcome!

A joint project between



European General Data Protection Regulation

GDPR



- Decided in April 2016
- The same law across all of Europe
- In force as from May 25, 2018
- National legislations will be cancelled – like the Personal Data Act (PUL)
- But much national legislation must be put in place for the GDPR to work
- At least 5 or 6 national government inquiries ongoing
- One deals with personal data in research (Forskningsdatautredningen 2016:04)
- June 2017 – adaptation of Swedish legislation for research in general
- December 2017 – new rules for databases (follow-up of Westerberg SOU 2014:45)

Scope of the regulation and pseudonymization

Article 4(5), Recital 26

The regulation applies to **personal data**

Personal data: directly or indirectly identifiable

Pseudonymized data: can no longer be attributed to a person
without the use of additional data

Pseudonymized data are personal data

Anonymized data are not included in the regulation

Where draw the line between pseudonymized and anonymized?

Principles of data protection: further processing

- Art 5.1b; Recitals 50, 156
- Cannot be used for purposes incompatible with the original purpose for which data were collected
- Research is not an incompatible purpose
- This is like now, but
 - Safeguards defined in Art 89, Rec 156 must be met
 - For special data (sensitive data) Art 9 must also be met
- Member States must define what the possible safeguards are

Principles of data protection: storage

- Art 5.1e
- Main rule.: No longer than necessary
- Exemption: data used only for scientific research, statistical or historical data can be kept longer
- This opens up for keeping the key longer

Lawfulness of processing

- Art 6(1): At least one of the following must apply:
 - (a) informed consent for one or more specific purposes
 - (b)
 - (c)
 - (d)
 - (e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller
 - (f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.
- Similar to now, but some important differences

Lawfulness of processing in the public interest

- Art 6(3): Processing for public interest must have a legal basis:
 - Solution 1: already defined in the law? (e.g. Högskolelagen says that the university shall perform research)
 - Question: what about private research organizations?
 - Solution 2: Write a new Swedish law for research?

Lawfulness of processing for legitimate interests

- Art 6(1)f, Recital 47
 - where the legitimate interests of the controller are not overridden by the interests of the data subject.
 - cannot be used by public bodies, e.g. public universities
 - Research has been considered legitimate interest
 - So this may be used by NGO:s

Lawfulness of processing by informed consent

- Art 6(1)a, Art 7, Recitals 33, 43
 - Conditions for consent are listed in Art 7 (similar to current rules)
 - Rec 33 opens up for **broader consent** than current Swedish rules do
 - But Rec 43 says: In order to ensure that consent is freely given, consent should not provide a valid legal ground for the processing of personal data in a specific case where there is a clear **imbalance** between the data subject and the controller, in particular **where the controller is a public authority** and it is therefore unlikely that consent was freely given in all the circumstances of that specific situation.
- Compared to today:
 - Wide purpose databases based on consent?
 - But: Can public universities/county councils etc. use consent at all?
If so, when?

Special categories of data

- Article 9
 - Current “sensitive data” (racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade-union membership)
 - In addition, **genetic data** and
 - **biometric data** for the purpose of identification of a natural person
- Processing forbidden unless:
 - **a. explicit** consent
 - (b), (c), (d), (e), (f)
 - (g) processing is necessary for reasons of **substantial public interest**, on the basis of Union or Member State law ...
 - processing is necessary for archiving purposes in the public interest, **scientific or historical research** purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law ...
- More data than today, similar rules

Individual rights

Exemptions

- Article 14(5)(b) provides an exemption for research from the requirement to provide **information** to the data subject where the data were *not* obtained directly from the data subject
- There is *no* exemption from the requirement to provide information to the data subject where the data were obtained directly from the data subject (Article 13). The information requirements have also increased significantly
- Article 17(3)(d) provides an exemption for research from the right to **erasure**.
- Article 21(6) limits any exception to the right to **object** for research to where the processing is necessary for a task carried out in the public interest.
- Similar to today

Article 89

Portal paragraph for research

- 1. Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards
- The following derogations and special provisions for research can only be used if these safeguards are in place:
 - - A.5(1)(b) and (e) - further processing and storage
 - - A.9(2)(j) - processing of special categories of data
 - - A.14 (5)(b) - information requirements
 - - A.17(3)(d) - right to erasure
 - - A.21(6) - right to object

Article 89

Necessary features of safeguards

- Anonymous data should be used instead of personal data where possible.
- Technical and organizational approaches must ensure the processing of personal data is limited to the minimum needed, which may include pseudonymization of data where possible.

Important outstanding questions

- What is research?
- What is research data?
- Who can do research?
- What is really pseudonymization?
- Can we have research databases based on “public interest”?

The Swedish Research Data Inquiry Tasks

- Analyse the need for safeguards
 - Propose safeguards
 - Should ethical vetting should be mandatory for all research using personal data?
 - Adapt the Law on Ethical Vetting
- Sensitive personal data and data on crimes/illegal acts
 - Is there a need for special regulation?
 - If yes, propose regulation

The Swedish Research Data Inquiry Tasks

- Adapt the Law on Ethical Vetting
 - Follow up the Register Research Inquiry (SOU 2014:45):
 - Analyse how applications are handled in the board
 - Consider simplified handling of cases with low integrity risk
- Adaption/replacement of some national register research legislation
 - The "Life Gene Law"
 - The Forensic Psychiatric Research Register
 - Protection for diseased persons in forensic research
 - The National Biobank Register
 - Long term regulation of research data bases

Staff and experts

- Head of inquiry
 - Cecilia Magnusson Sjöberg, prof legal informatics SU
- Secretaries
 - Staffan Malmgren, legal expert (lagen.nu)
 - Magnus Stenbeck, assoc prof KI
 - Linda Stridsberg, chief legal officer FORMAS
- Experts appointed by the government
- Informal reference group