

'Big data analytics' and processing of health data for scientific research purposes : the Swedish legal framework

Research Protocol by Christine Storr, Faculty of Law, Stockholm University, and Pam Storr, Independent Legal Consultant and Teacher in IT law
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1. Overview of the legal framework

First, we would like to get an overview of the current and upcoming legal framework applying to the processing of health data for research purposes in your country.

a. Which laws regulate the processing of health data for research purposes (the current regime, in force till 25 May 2018)

What are the relevant applicable provisions governing the processing of health data in your country? Please provide online references (also to an English version, if available), a brief description and any specific relevant information.

With regards to health data, there are two main laws that are applicable, the Personal Data Act [*Personuppgiftslag (1998:204)*]¹ which transposed Directive 95/46² and which is generally applicable to all types of data processing, and the Patient Data Act [*Patientdatalag (2008:355)*] which is specifically applicable to health data processing carried out by private or public healthcare providers.

In addition, the Swedish Patient Security Act [*Patientsäkerhetslag (2010:659)*] and the Public Access to Information and Secrecy Act (OSL) [*Offentlighets- och sekretesslag (2009:400)*] stipulate requirements for healthcare providers regarding security and confidentiality, though OSL only applies to public authorities.

Section 19 of the Personal Data Act states that sensitive data can be used for research purposes if the processing has been approved according to the Act (2003:460) concerning the Ethical Review of Research Involving Humans (Ethical Review Act) [*Lag (2003:460) om etikprövning av forskning som avser människor*]³. As health data is considered sensitive data all research projects that process health related data must go through the vetting process by the Ethical Review Board.⁴

Public authorities' processing of personal data is commonly regulated in designated statutes. These statutes are generically called database laws or register statutes (*registerförfattningar*) and regulate the conditions under which processing is allowed, which principles should be followed, which authority is responsible, who can access the data and how long the data should be kept. Some examples of these database laws within the healthcare sector will be mentioned below.

The Swedish Research Council (*Vetenskapsrådet*) has published information to help researchers when trying to access data for research purposes. The website is available in Swedish at <https://www.registerforskning.se/>.

¹ An older English translation is available at <https://www.datainspektionen.se/in-english/legislation/the-personal-data-act/>

² [Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.](#)

³ An English translation is available at <https://www.epn.se/en/start/regulations/>

⁴ <https://www.epn.se/en/start/>

Main legislation on databases containing health data

When it comes to the structure of the healthcare sector, there are two main possibilities for databases containing health data. One concerns databases kept by healthcare providers, so-called quality registers (*kvalitetsregister*), and the other one concerns biobanks which can be administered by both private and public healthcare providers.

Quality registers

The quality registers have been established in Sweden for a while with the goal to increase the quality of healthcare. There are around 100 quality registers which contain data on health problems, diagnoses, treatment and results.⁵ The registers are integrated into clinical workflows and can generate data in real time. A group of healthcare professionals, researchers and patient representatives supports each register.⁶ Registers can be focused either on patients with a specific illness, or on a specific treatment or risk group. Therefore, the quality registers can differ with regards to level of coverage and data quality.

The National Board of Health and Welfare (*Socialstyrelsen*) administers some of the registers, e.g. the national patient register (NPR)⁷, and offers support for accessing other registers.⁸ The NPR has existed for approximately 50 years and contains both patient data (the Swedish personal identity number, gender, age, place of residence), geographical data (which county, which hospital), administrative data (date of admission, date of discharge, etc.) and medical data (main diagnosis, secondary diagnosis, external cause of injury). Healthcare providers (both public and private) must submit information into the NPR.

In general, the registers are decentralised and often administered by healthcare providers in different regions. In most cases, personal data is being collected through the patient journal.

The quality registers are covered by Chapter 7 of the Patient Data Act. Section 7 states that only public authorities may be data controllers, although the government can allow for exceptions to this principle. According to Section 5 in Chapter 7 personal data in a national or regional quality register may be used for research or statistical purposes. Researchers can apply to use data from the quality registers.⁹

The registers kept by the National Board of Health and Welfare (*Socialstyrelsen*), e.g. NPR, are also regulated in the Act on Health Data Registers (*lagen (1998:543) om hälsodataregister*) and several regulations, e.g. Regulation on Patient Registers with the National Board of Health and Welfare (*Förordning (2001:707) om patientregister hos Socialstyrelsen*). They are also covered by strict secrecy according to the Public Access to Information and Secrecy Act [*offentlighets- och sekretesslag (2009:400)*].

Biobanks

⁵ A list is available in English at <http://www.kvalitetsregister.se/englishpages/findaregistry/allswedishqualityregistries.2028.html>

⁶ Read more in English at the official page at <http://www.kvalitetsregister.se/englishpages.2040.html>

⁷ Information in English available at <http://www.socialstyrelsen.se/register/halsodataregister/patientregistret/inenglish>

⁸ more information in Swedish at <http://www.socialstyrelsen.se/register> and a shorter overview at <http://www.socialstyrelsen.se/statistics>

⁹ A detailed overview of the application process is available in English at <http://www.kvalitetsregister.se/englishpages/userregistrydatainyourresearch/quickguideforresearchers.2409.html>



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The Act on Biobanks within Health and Medical Care (Biobank Act) (*lagen (2002:297) om biobanker i hälso- och sjukvården m.m.*)¹⁰ regulates how human tissue can be collected, stored and used. According to the Act (Chapter 2 Section 2) biobanks can only be established for healthcare, treatment and other medical purposes as well as quality assurance, training, research, clinical trials, development or other equivalent activities. If the biobank is mainly to be used for research and clinical trials, it may only be established after approval by the Ethical Review Board (Chapter 2 Section 3 Biobank Act). The biobank may not be used for purposes other than those approved by the Board.

Biobanks have to be reported to Health and Social Care Inspectorate (IVO) (*Inspektionen för vård och omsorg*)¹¹ according to Chapter 2 Section 5 Biobanks Act. Today there are around 450 biobanks registered with IVO. Around 200 of these are kept by counties and contain around 90 % of all samples stored.¹² It is, however, possible for private entities to administer a biobank, with the rules of the Biobank Act being applicable.

Biobank Sweden coordinates the various biobanks in the country and administers a catalogue over research sample collections.¹³ It also publishes guidelines and templates for contracts for access to the biobanks.

Legislation concerning human tissue

The Transplant Act [*lagen (1995:831) om transplantation m.m. (transplantationslagen)*] regulates all types of intrusion made on living or deceased humans for medical purposes. As these intrusions are carried out within healthcare, the Biobank Act is also applicable.

The Act on Blood Safety (*lagen (2006:496) om blodsäkerhet*)¹⁴ applies for collection, production, control or storage of blood or components of blood to be used for a transfusion. If blood or components of blood are to be used as raw material for the production of medicine or technical products the Act on Medical-Technical Products (*lagen (1993:584) om medicintekniska produkter*) as well as the Medicine Act (*läkemedelslagen (2015:315)*) apply.

The Genetic Integrity Act (*lagen (2006:351) om genetisk integritet m.m.*)¹⁵ deals specifically with the use of genetic investigations, genetic information and gene therapy. The Act contains provisions on e.g. whether genetic information can be requested by insurance companies and stipulates requirements for genetic investigation. The Act also deals with pre-natal and pre-implantation genetic diagnosis, research using human eggs, insemination, and fertilisation outside the body.

¹⁰ An unofficial English translation is available as a pdf at <http://biobanksverige.se/wp-content/uploads/Biobanks-in-medical-care-act-2002-297.pdf>

¹¹ <https://www.ivo.se/om-ivo/other-languages/english/>

¹² More information in English at Biobank Sweden <http://biobanksverige.se/research/basic-information-in-english/> Biobank Sweden (former National Biobank Council (*Nationella biobanksrådet*) and BBMRI.se is a cooperation between counties and universities with a medical faculty, dealing with biobank questions.

¹³ in Swedish at <http://biobanksverige.se/forskning/nationell-katalog-over-forskningsprovsamlingar/>

¹⁴ The Act is based on [Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.](#)

¹⁵ An unofficial translation is available at <http://www.smer.se/news/the-genetic-integrity-act-2006351/>



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Finally, the Autopsy Act [*lag (1995:832) om obduktion m.m.*] regulates the circumstances under which autopsies are allowed. The principle according to Section 5 is that organs and other material can be taken out of the body for examination if necessary for the autopsy. Biological material should be returned when the autopsy is finished unless the aim of the autopsy requires the material to be looked at for a longer period of time. In this case, the Biobank Act applies for the material.

Acts with Specific Purposes

The Act on Certain Databases for Research on what Inheritance and Environment means for Humans' Health [*Lagen (2013:794) om vissa register för forskning om vad arv och miljö betyder för människors hälsa*] applies to universities processing healthcare data for research purposes. The Act is a result of a decision by the Swedish data protection supervisory authority, the Data Inspection Board (*Datainspektionen*), declaring that consent was not specific nor informed enough for individuals participating in the international LifeGene project.

The Act on Quality and Security Norms when Processing Human Tissue or Cells [*Lagen (2008:286) om kvalitets- och säkerhetsnormer vid hantering av mänskliga vävnader och celler (vävnadslagen)*]¹⁶ applies when human tissue or human cells are processed for use on humans or for the production of medicine for humans.

b. Revision of the current legal framework under the GDPR

How are the necessary changes to the national data protection framework introduced by the GDPR addressed in your country? What is the adopted legislative approach?

A few governmental inquiries are assessing whether and how existing data protection legislation should be amended, repealed or enacted due to the GDPR. Some of the more specific inquiries with regards to healthcare and the research sector have led to Governmental Reports (SOU) between autumn 2017 and spring 2018. The Research Data Inquiry Committee (*Forskningsdatautredningen*) published its Governmental Report (SOU) 2017:50 in May 2017¹⁷, and a final Governmental Report (SOU) 2018:36 in June 2018¹⁸; another Committee published the Governmental Report (SOU) 2018:4 Future Biobanks¹⁹ in December 2017. The Research Data Inquiry Reports SOU 2017:50 and SOU 2018:36 are being drafted into a Government Bill currently (August 2018), so it is not clear at this time when the proposed new Act on Research Databases (*forskningsdatabaslagen*) will be enacted.

¹⁶ The Act is based on [Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.](#)

¹⁷ The report with an English summary is available at www.regeringen.se/rattsdokument/statens-offentliga-utredningar/2017/06/sou-201750/

¹⁸ The report with an English summary is available at www.regeringen.se/rattsliga-dokument/statens-offentliga-utredningar/2018/06/sou-201836/

¹⁹ The report with an English summary is available at www.regeringen.se/rattsdokument/statens-offentliga-utredningar/2018/01/sou-20184/



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The Social Data Protection Inquiry Committee has assessed, inter alia, the Patient Data Act and its compatibility with the GDPR; it published the Governmental Report SOU 2017:66²⁰ which has led to a Government Bill *Prop. 2017/18:171 Dataskydd inom Socialdepartementets verksamhetsområde – en anpassning till EU:s dataskyddsförordning*²¹. As of August 2018, the proposed changes have not yet been enacted.

The general inquiry looking into supplemental rules complementing the GDPR published the Governmental Report (SOU) New Data Protection Act SOU 2017:39 (with an English [summary](#)), followed by a Government Bill *Prop. 2017/18:105, Ny dataskyddslag*, on 15 February 2018²². The Swedish Parliament enacted new legislation on 25 May 2018 as a result; in total three pieces of legislation were enacted: Act containing supplementary provisions to the EU General Data Protection Regulation (*Lag (2018:218) med kompletterande bestämmelser till EU:s dataskyddsförordning*) – in short Data Protection Act (*dataskyddslag*), Ordinance containing supplementary provisions to the EU General Data Protection Regulation (*Förordning (2018:219) med kompletterande bestämmelser till EU:s dataskyddsförordning*), and Act amending the Public Access to Information and Secrecy Act (*lag (2018:220) om ändring i offentlighets- och sekretesslagen (2009:400)*).

The main inquiries within the health and research sector do not all necessarily focus on the GDPR but rather take a wider approach and discuss potential pitfalls with the current regulation on research data and biobanks respectively and aiming to improve the general legal framework.

c. The national data processing authority

Can you provide a short description of the role of the data protection supervisory authority in your country in the domain of processing health data for research purposes under the current legal framework?

The Swedish Data Inspection Board (*Datainspektionen*)²³ is the responsible supervisory authority with regards to data protection. The authority is also responsible for supervising the application and implementation of the Swedish Patient Data Act, and its remit therefore includes processing of health data.

The Personal Data Act includes an obligation to notify the Data Inspection Board of the processing of personal data before any processing begins. Researchers must therefore register with the Board according to Section 36 Personal Data Act. However, according to the Data Inspection Board's regulations, notification is not required where individuals have consented to the processing. The Personal Data Act also provides for an exception to registration where a data protection officer is appointed and registered with the Board. After implementation of the GDPR, organisations that process a large amount of data or particularly sensitive data are required to register a data protection officer with the Board according to Article 37 (7) GDPR.

²⁰ <http://www.regeringen.se/rattsdokument/statens-offentliga-utredningar/2017/08/sou-201766/>

²¹ <http://www.regeringen.se/rattsdokument/proposition/2018/03/prop.-201718171/>

²² Available in Swedish at www.regeringen.se/rattsdokument/proposition/2018/02/prop.-201718105/

²³ www.datainspektionen.se



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Within the health sector, the main supervisory authority is the Swedish government agency Health and Social Care Inspectorate (*Inspektionen för vård och omsorg – IVO*)²⁴. The Inspectorate's task is to supervise that the public receives safe, good quality health and social care. Healthcare providers must register with the Inspectorate, in accordance with Chapter 2 Section 1 of the Swedish Patient Security Act [*Patientsäkerhetslag (2010:659)*].

The National Board of Health and Welfare (*Socialstyrelsen*)²⁵ is also involved in health and social care, particularly eHealth. The Board is mentioned in the Patient Data Regulation [*Patientdataförordning (2008:360)*] as one of the responsible authorities for patient data issues; one of its main tasks is to build a basis for documentation and interoperability.

Can you describe the adopted or proposed changes to this role of the national data protection authority to ensure compliance with the GDPR?

The Government Bill *Prop 2017/18:105, Ny dataskyddslag* suggests that the Swedish data protection authority, i.e. the current Data Inspection Board, has to consider complaints within three months, in accordance with the timeframe set out in the GDPR. The Bill also suggests that it should be possible to impose administrative fines on an authority that does not adhere to the GDPR; this has been adopted in Chapter 6 Section 2 paragraph 1 of the new Data Protection Act. In general, decisions taken by the supervisory authority can be appealed to an administrative court.

The Research Data Inquiry Committee proposes in SOU 2017:50 and 2018:38 that the Swedish Data Inspection Board should also be the supervisory authority for the new Research Data Act.²⁶

In a press release, the Government has stated that it will increase the annual budget of the Data Inspection Board by SEK30 million (about €3 million) and has proposed that the name of the Board will change to the Privacy Protection Authority (*Integritetsskyddsmyndigheten*).²⁷

2. Transposition of Article 8.4 of Directive 95/46

Did your national legislator insert any additional exemptions for the processing of health data for research purposes? How is it/are they formulated? Please explain. Are there additional exemptions issued by the DPA?

²⁴ www.ivo.se. The Inspectorate was created in June 2013 and took over the supervisory activities of the National Board of Health and Welfare (*Socialstyrelsen*). It therefore now supervises health and medical care as well as social services.

²⁵ www.socialstyrelsen.se/english

²⁶ SOU 2017:50 pp 36-37 and SOU 2018:38 p 31.

²⁷ Press release by the Government (15 December 2017) <<http://www.regeringen.se/pressmeddelanden/2017/12/datainspektionen-blir-integritetsskyddsmyndigheten/>> accessed 15 January 2018 (in Swedish).



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Article 8.4 of Directive 95/46: “Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority.”

a. Transposition of Article 8.4 of Directive 95/46

In Sweden, data concerning health is classed as sensitive personal data and as such its processing is prohibited according to Section 13 (2) of the Personal Data Act. However, exceptions to this prohibition are permitted in accordance with Section 14, and these grounds are found in Sections 15-19 of the Act. Processing of sensitive data is permitted under Swedish law where for example a data subject has expressly consented (Section 15); where processing is necessary for medical purposes (Section 18) (this provision encompasses preventive healthcare, medical diagnoses, care or treatment, and the administration of healthcare); and processing for research and statistical purposes (Section 19).

Processing of sensitive personal data for research purposes is therefore expressly permitted in Sweden due to Section 19 Personal Data Act. However, Section 19 (1) states that such processing must be authorised in accordance with the Act concerning the Ethical Review of Research Involving Humans (*lagen (2003:460) om etikprövning av forskning som avser människor*, Ethical Review Act). The Ethical Review Act also defines the term “research” purposes.²⁸

According to Section 20 Personal Data Act, the government or supervisory authority may issue further exemptions from the prohibition to process sensitive data (including health data) “where necessary for reasons of substantial public interest”.²⁹ The Data Inspection Board has however not issued any specific regulations in accordance with this provision.

It was noted in the preparatory works when transposing the Directive that the Swedish constitutional principle of openness (*offentlighetsprincipen*) was considered a substantial public interest and therefore an exemption foreseen in Article 8.4 of the Directive. There was deemed to be no obstacle in the application of existing Swedish rules on access to public documents, leading to a requirement of notification to the Commission pursuant to Article 8.6.³⁰ Archival was also deemed to be a substantial public interest; as archival of public documents can include sensitive personal data, a legal provision was deemed necessary, leading again to a requirement of notification to the Commission pursuant to Article 8.6.³¹

These two issues (access to public documents and archiving) have been included in the national law and are found in Section 8 Personal Data Act. Section 8 (1) states that the provisions of the Personal Data Act shall not apply in cases where they would restrict an authority’s obligations according to Chapter 2 of the constitutional Freedom of

²⁸ Section 2 Ethical Review Act defines “research” as scientific, experimental or theoretical work to obtain new knowledge, and also developmental work carried out on a scientific basis, with the exception of that which is carried out as part of a programme of study at an institute of higher education.

²⁹ Government Bill 1997/98:44 p. 127 states that the Swedish wording “viktigt allmänt intresse” shall have the same meaning as in Article 8.4 Directive 95/46 (i.e. a reason of substantial public interest).

³⁰ Governmental Report 1997:39 p. 215-216; Government Bill 1997/98:44 p.44

³¹ Governmental Report 1997:39 p. 220; Government Bill 1997/98:44 p.47-48



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the Press Act to disclose personal data; Section 8 (2) states that the provisions of the Personal Data Act do not prevent an authority from archiving or storing public documents, or from being handled by an archiving authority.

b. The regime applying to the processing of personal data for health research purposes

Is there a specific regime applying to data processing for research in the field of health purposes?

The Ethical Review Act, mentioned above, is the main piece of legislation relating to research in the field of health purposes in Sweden. The Act encompasses research involving humans (both living and deceased persons), biological material from humans, along with processing of sensitive personal data and personal data concerning criminal offences (Sections 3 and 4 Ethical Review Act). The aim of the Act, according to Section 1 (2), is to protect individuals and human dignity when research is conducted. Personal data processing for research in the field of health research purposes therefore forms a part of this wider-ranging Act relating to research involving humans.

All research referred to in the Ethical Review Act may only be conducted where approval has been granted following an ethical vetting (Section 6 Ethical Review Act). Research involving the processing of personal data is only allowed where approval for this processing has been given as part of the ethical vetting. Approval is valid for two years, meaning that the research must be commenced within this time period. For approval to be given, research must meet certain conditions, for example be conducted or supervised by a researcher with the necessary competence (Section 11), and be of sufficient scientific value to outweigh any risks to the research subject's health, safety and personal integrity (Section 9). Approval cannot be given where the anticipated result can be achieved through other means that entail fewer risks to the research subject's health, safety or personal integrity (Section 10 (1)). In addition, research involving the processing of sensitive personal data may only be approved if such processing is necessary for the research to be carried out (Section 10 (2)).

Personal data (of a non-sensitive nature) may also be processed according to Section 10 (d) Personal Data Act, where it is deemed necessary for the public interest. Such public interest includes archiving, research and statistics. Previously, when Directive 95/46 was transposed, this provision even applied to sensitive personal data; sensitive data could therefore be used for research purposes provided that the public interest of such research clearly outweighed the risk for any violation of the individual's privacy.³² Following an amendment to the Personal Data Act in 2003, this possibility was removed and the system of ethical research vetting was applied to sensitive data, as detailed above.

To the extent the research includes the collection of personal data, other legislation such as the Biobank Act and other laws mentioned in Chapter I A in this report may be applicable.

³² See Government Bill 1997/98:44 p.68.



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From which generally applicable data protection provisions are researchers exempted and under what conditions?

In general, researchers are not exempted from the generally applicable data protection provisions. One exemption is provided for in Section 24 (3) Personal Data Act, in relation to informing an individual of the processing of their personal data. According to this provision, information does not need to be provided where it would not be possible or would involve disproportionate efforts. In relation to research this section can be applied in line with Recital 40 Directive 95/46, taking into account for example the number of data subjects and the age of the data.

Although not an explicit exemption, the common interpretation of the Biobank Act has been that storing tissue samples in biobanks does not amount to processing of personal data as such.³³ The Act distinguishes between tissue samples and personal data connected to the samples. The databases that are connected to the biobanks do contain personal data and therefore must be processed in accordance with the Personal Data Act.

c. Are there additional specific conditions governing the processing of data for scientific research purposes?

What are the suitable safeguards applied to the exemption foreseen by Article 8.4 of the Directive in your country?

As mentioned above, Section 19 (1) Personal Data Act permits the processing of sensitive personal data for research purposes only after approval in accordance with the Ethical Review Act. There are, however, no specific security measures applicable to sensitive personal data. Rather, the general security provisions apply, following the transposition of Article 17 Directive 95/46 regarding appropriate technical and organisational measures to protect personal data that is processed. Section 31 Personal Data Act specifies that the measures shall provide a level of safety that is appropriate considering the technical possibilities that are available, the implementation costs of particular measures, the risks associated with the processing and how sensitive the data is that is being processed. In general terms, the more sensitive the data the higher the security measures. The Data Inspection Board has issued guidelines on the required level of protection.³⁴

Section 9 (4) Personal Data Act has been deemed a suitable safeguard to the exemption foreseen by Article 8.4 Directive 95/46.³⁵ The section states that data processed for scientific purposes may only be used for measures regarding the data subject if the data subject has given consent or there are special reasons due to the vital interests

³³ SOU 2018:4, p 93 with further references, including Article 29 Working Party Opinion N° 4/2007 - WP 136

(20.06.2007), p 8-9.

³⁴ Available in Swedish at <https://www.datainspektionen.se/Documents/faktabroschyr-allmannarad-sakerhet.pdf>.

³⁵ Government Bill 1997/98:44 p.119-120.

of the data subject. It is for the data controller to show that special reasons exist. Section 9 (4) does not apply, however, in cases where an authority uses personal data in public documents.³⁶

Specific examples are mentioned in the Governmental Bill, to illustrate when vital interests of the data subject would allow for data to be used that has been processed for scientific purposes.³⁷ The first example is where a researcher investigating a potential link between a particular medicine and a serious illness finds an actual link and therefore uses data to warn research subjects who have taken such medicine so that they can be examined and receive treatment. The second circumstance is where a statistical register is used to warn those who have purchased a device found to have a serious error. These examples suggest that Section 9 (4) this provision is somewhat limited in practice, as both involve a danger to life or risk of injury.

In addition, existing Swedish rules on confidentiality and professional secrecy that are generally applicable to research and statistics are also considered to be suitable safeguards.³⁸ For example, Chapter 21 Section 1 Public Access to Information and Secrecy Act (OSL) [*Offentlighets- och sekretesslag (2009:400)*] states that confidentiality applies to information pertaining to an individual's health or sex life, such as information about illness or abuse. In addition, Chapter 21 Section 7 OSL states that confidentiality applies where disclosure would result in personal data being processed in a manner contrary to the provisions of the Personal Data Act. Chapter 11 Section 3 OSL states that if an authority, as part of its research activities, receives data from another authority that is classified as confidential, this confidentiality will apply to the data at the receiving authority. The Ethical Review Act also refers to rules on confidentiality and professional secrecy, stating in Section 12 that personal data may be disclosed for research purposes unless otherwise provided by such rules.

In relation to the use of sensitive data for scientific research purposes, the ethical vetting procedure must be followed, as detailed above. There is a presumption made in Section 19 Personal Data Act that where approval of personal data processing has been granted by the ethical vetting board, in accordance with the provisions of the Ethical Review Act, the public interest following of the research outweighs the risk for undue violation of individual privacy. In other words, the ethical vetting procedure is in itself a sufficient suitable safeguard.³⁹ However, this was initially a voluntary approval procedure; where no ethical vetting took place, there was a requirement under the Personal Data Regulation (1998:1191) for the research's data controller to carry out an assessment and notify the Swedish Data Protection Board of the processing a minimum of three weeks in advance so that a prior check could be carried out. Assessment by the researchers themselves is no longer necessary, due to the now mandatory nature of the ethical vetting procedure.⁴⁰

Are there any specific provisions concerning: (i) professional secrecy, (ii) express consent for specific data, or specific provisions for (iii) deceased data subjects, or (iv) specific provisions for minors or persons subject to guardianship?

³⁶ Section 8 (2) Personal Data Act. See also above on exemptions for public authorities relating to the constitutional principle of openness.

³⁷ Government Bill 1997/98:44 p.120.

³⁸ Government Bill 1997/98:44 p.69

³⁹ See Government Bill 1997/98:44 p.71.

⁴⁰ See further Government Bill 2002/03:50 p. 173.



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Professional secrecy

The applicable rules on professional secrecy are dependent upon the organisation carrying out the research. The Swedish principle of openness (*offentlighetsprincipen*) applies to public healthcare providers and research institutions, entailing a presumption of access to public documents. This presumption, however, can be negated due to reasons of confidentiality and secrecy, in accordance with the Public Access to Information and Secrecy Act (OSL) [*Offentlighets- och sekretesslag (2009:400)*]. Chapter 24 OSL regulates secrecy in the area of research and statistics. Accordingly, documents are not permitted to be handed out if they are subject to professional secrecy.

The principle of openness does not apply to private healthcare providers, nor the rules contained in the Public Access to Information and Secrecy Act (OSL). Instead, provisions on professional secrecy are found in the Patient Safety Act (*Patientsäkerhetslagen (2010:659)*), and are intended to give the same protection as under the OSL provisions. However, the protection only extends to healthcare, not to research.⁴¹ There is therefore no legislative provision on professional secrecy for research carried out by private healthcare providers. In these instances such professional secrecy is regulated by contract.⁴² The Governmental report (SOU) 2018:38 proposes, however, an obligation for private research organisations to observe professional secrecy, to be included in the new Act on Research Databases (*forskningsdatabaslagen*).

Express consent

The research subject must consent to research according to Section 17 Ethical Review Act; this consent must be voluntary, explicit and specific, given after receiving information on the research detailed in Section 16, and be documented. Exceptions to the consent requirement exist, due to for example illness or mental disorder, and these are detailed in Sections 20-22.

According to the Biobank Act consent must be explicit and documented in the patient's journal (Chapter 3 Section 7). One of the principles of the Biobank Act is informed consent; if the tissue donor withdraws her or his consent, the biobank must either destroy or anonymise the sample (Chapter 3 Section 6).

According to the Transplant Act, biological material can only be taken for medical purposes if the data subject has consented. If there is a risk of damages, the consent has to be in writing (Section 6).

Deceased data subjects

Neither the Ethical Review Act nor the Biobank Act contain any provisions on consent or information when it comes to deceased data subjects, but refer to the Transplant Act and the Autopsy Act (Section 13 (2) Ethical Review Act and Chapter 3 Section 4 Biobank Act). The Autopsy Act mainly deals with the question when an autopsy may be carried out, not with questions on research.

According to the Transplant Act biological material may be taken if the deceased has consented or if the procedure can be assumed to be in line with her or his beliefs. Biological material can also be taken if the deceased has *not* opposed the procedure/surgery in writing or spoken out against the procedure, or if there are reasons to assume the procedure would be against the deceased's beliefs. If there is any doubt, the procedure should be not performed (Section 3). In case the deceased's next of kin opposes the procedure, it should not be undertaken (Section 4).

⁴¹ Governmental Report 2017:50 p.274. See Chapter 6 Section 12 PSL.

⁴² Governmental Report 2018:4 p. 111.



Partners

The Research Data Inquiry Committee discusses in Governmental Report (SOU) 2018:36 research on deceased persons. The Committee did not suggest any changes to the legislative framework in this regard and found that the existing legislation along with its proposal for research secrecy provides sufficient protection for data about deceased persons.⁴³

Minors and persons subject to guardianship

For minors, specific consent provisions apply according to Section 18 Ethical Review Act. For research subjects between the ages of 15-17, who understand the implication of the research, the general information and consent provisions apply. In other cases involving minors, the legal custodians are to be informed and must consent to the research in accordance with the provisions of the Act. The research subject is however, as far as possible, to be informed of the research. According to Section 18 (2), even in cases where a custodian consents, research may not be conducted where a research subject under the age of 15 understands the implications of the research and opposes it.

The Biobank Act does not specify any particular age but also follows the same principle that the parent or guardian should be asked for consent unless the minor is able to make such a decision herself (Chapter 3 Section 2).

In relation to persons subject to guardianship, Section 20 Ethical Review Act allows for research to be conducted without consent in cases of illness, mental disorder, impaired health or other similar circumstance. However, certain conditions must be met in these cases, in accordance with Section 22. The individual shall, as far as possible, be personally informed of the research, consultation with the individual's next of kin and any legal guardian must take place, in accordance with Chapter 11 Parental Code [*Föräldrabalken (1949:381)*]. The research may not be conducted where the research subject in any way expresses a wish not to participate or if any of those consulted oppose the research.

Are there specific requirements about the data subject's information or about the person from whom the data was collected?

The research subject is to receive information about the research in accordance with Section 16 Ethical Review Act, on for example the purpose of the research, the methods used, the consequences and risks the research may entail, the responsible research body, the voluntary nature of participation and the right of the research subject to cease participation at any time.

Are there specific penalties if the conditions for processing for scientific research in the field of health purposes are not respected? What do those penalties entail?

Intentional violation of the provisions of the Ethical Review Act can result in fines or imprisonment for a maximum of six months; minor violations will, however, not lead to any sanction.⁴⁴

⁴³ SOU 2018:38 pp 35.

⁴⁴ Section 38 Ethical Review Act.

Intentional or negligent violations of the Personal Data Act can result in fines or imprisonment for a maximum of two years. As for the Ethical Review Act, minor violations will not lead to any sanction.⁴⁵ Compensation can also be paid to the individual for injury and violations of personal integrity caused by any processing contrary to the provisions of both the Personal Data Act⁴⁶ and the Biobank Act⁴⁷.

In cases of violation of professional secrecy (*“brott mot tystnadsplikt”*) Chapter 20 Section 3 of the Swedish Penal Code (*Brottsbalk* (1962:700)) will be applicable; this can result in fines or imprisonment for a maximum of one year.

d. Formalities prior to processing: the general regime under the current framework

Is there a regime requiring the fulfilment of certain conditions prior to any processing activities different from that applicable to research in the field of health? If yes, what does that regime entail?

As stated above, all research referred to in the Ethical Review Act may only be conducted where approval has been granted following an ethical vetting. Research involving the processing of personal data is only allowed where approval for this processing has been given as part of the ethical vetting. In addition, research subjects must consent to the research in question, as detailed above.

Since 2004, there is one central ethical vetting board and six regional boards. Each regional board is responsible for its own geographically defined catchment area; applications for research approval should therefore be made to the relevant regional board.⁴⁸ Changes are to be made to the current system, effective 1 January 2019, whereby the regional boards are to be phased out and the responsibility for ethical vetting will instead fall on a new central authority. The reason for this change is to increase efficiency and create a more uniform application of the legal framework.⁴⁹

An application must be made for research approval and a fee paid by the person responsible for the research. A written procedure is generally used by the boards. At the meetings, any one of three decisions can be made: an application may be approved, approved subject to certain conditions or rejected. The regional boards should normally make a decision within sixty (60) days of receiving a fully completed application.

⁴⁵ Section 49 Personal Data Act.

⁴⁶ Section 48 Personal Data Act.

⁴⁷ Chapter 6 Section 2 Biobank Act.

⁴⁸ For more information on the ethical vetting organisation see the Central Ethical Review Board’s website, <https://www.epn.se/en/start/the-organisation/>.

⁴⁹ See Government Bill 2017/18:45 (*Prop. 2017/18:45 En ny organisation för etikprövning av forskning som avser människor*).



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3. Further processing of health data (for research purposes): the current regime

How is the notion of further processing regulated in your national framework?

Further processing is regulated in Section 9 (1)(d) Personal Data Act. Further processing is only allowed where compatible with the original purpose for which the data was collected. Data must be collected for a specific purpose (Section 9 (c)) and can therefore not be processed in a manner that is incompatible with this purpose.

Are there specific conditions to the further processing for scientific research in the field of health purposes?

The Swedish Personal Data Act includes a specific provision on the further processing of data for scientific purposes. Section 9 (2) states that further processing of data for historical, statistical or scientific purposes shall not be deemed incompatible with the initial purpose of collection. Further processing for scientific research purposes is therefore permitted under the Swedish framework.

Personal data is not permitted to be retained for longer than necessary for the purpose of processing (Section 9 (1)(i)). However, personal data can be retained a longer period of time for historical, statistical or scientific purposes, provided that it is not retained for longer than necessary for such historical, statistical or scientific purposes, in accordance with Section 9 (3).

The newly enacted Data Protection Act does not contain a similar section on this question but allows processing of health data in Chapter 3 Sections 2-7 in accordance with Article 9 (2) GDPR if the processing is based on an important public interest. The Act does not mention scientific purposes anymore, however.

Chapter 4 of the Biobank Act regulates sharing of tissue samples. According to Section 4 tissue samples that are shared shall be depersonalised or coded. According to Section 10 personal details may not be linked to the tissue samples if both are shared at the same time.

What are the rights of the data subject when it comes to further processing?

The data subject has a right to be informed of processing and further processing, in accordance with Sections 23-25 Personal Data Act. The data controller must inform the data subject about: its identity, the purpose of the processing, and other information needed so that the data subject can take advantage of their rights in connection with processing, such as information on the recipients of the data, the obligation to provide information and the right to apply for the correction of data.⁵⁰ Information does not need to be provided that is already known by the data subject.⁵¹ There is no requirement to provide the information in writing, but it is the data controller who must prove that the information has been given.

Section 24, described earlier, deals specifically with the rights of the data subject for further processing. The data controller must inform the data subject, if the data was not collected from him/her, about the processing of data at

⁵⁰ Section 25 (1) Personal Data Act.

⁵¹ Section 25 (2) Personal Data Act.

the time when the data is registered. However, Section 24 (2) provides an exemption to the information requirement where provisions on the registration or disclosure of personal data are included in another law or regulation. Furthermore, the information does not need to be provided, as mentioned previously and stated in Section 24 (3), where it would not be possible or would involve disproportionate efforts.

The newly enacted Data Protection Act does not contain similar sections in this regard so the GDPR is applicable.

What about the data subject's rights and further processing for scientific research purposes?

As no general exemptions from the data protection provisions exist for research purposes, the relevant provisions are those mentioned above, namely Section 24 Personal Data Act. There is a potential exemption for researchers to inform data subjects if this would involve disproportionate efforts, as mentioned above and as in line with Recital 40 Directive 95/46.

4. The GDPR's impact on the current regulatory framework for the processing of health data for research purposes

a. The impact of the GDPR on the rules applying to processing for research in the field of health

Please provide a summary of the main relevant characteristics of the new law/Bill (as far as it is relevant for processing health data for research purposes). How is (or will be) Article 9(2)(j) implemented in your country?

The Government Bill for a new data protection act (*Prop 2017/18:105, Ny dataskyddslag*) briefly discusses data processing within healthcare but does not mention research in any more detail, and refers to the Research Data Inquiry Committee (*Forskningsdatautredningen*) and the Governmental Report (SOU) 2017:50. Research purposes are not mentioned in the new legislation enacted by the Swedish Parliament in 2018.

The Research Data Inquiry Committee proposes the introduction of a new Research Data Act (*forskningsdatalag*) "with the purpose of enabling personal data to be processed for the purpose of research and to protect the freedoms and rights of the individual in conjunction with such processing of personal data."⁵² Though SOU 2017:50 was followed up by a final Governmental report SOU 2018:38 and is currently drafted into a Government Bill, it is not yet clear to what extent changes will be made in the final law. Among the notable suggested changes is a provision enabling both public and private research actors to cite "task carried out in the public interest" as the legal basis for processing personal data for research purposes (Article 6 (1) (e) GDPR). According to Article 6 (3) GDPR public interest must be based on EU or national law. For public research actors, the legal basis are statutes that stipulate research as a main task, e.g. for universities Chapter 1 Section 2 Higher Education Act (*högskolelagen*). For private

⁵² Governmental Report 2017:50, p 30.

actors, SOU 2018:38 proposes that a public interest is established if the private research actor has received approval for its research database through the ethical review procedure.⁵³

According to Chapter 2 Section 3 of the proposal for a Research Data Act, sensitive data may be processed according to Article 9 (2)(j) GDPR if the processing has been approved in accordance with the Ethical Review Act and the research actor has secured financing for the research database. The Ethical Review Act stipulates further requirements for the vetting procedure. According to the proposal the Act allows personal data to be processed in research databases in order to be used and shared in future research projects. Both the research database and the research project must be approved by an ethical review.

Another notable change is a provision stating that personal data must be pseudonymised or protected in an equivalent manner when processed for research purposes, provided that the purpose can be attained by doing so.⁵⁴

Another point worth mentioning is that SOU 2018:38 discusses the possibility for Swedish research organisations to share research databases with other EU organisations. According to the proposal, the Governmental Inquiry suggests a secrecy override applicable to research databases operated by research organisations which are covered by the GDPR. This override would mean that, under certain conditions, data that is subject to secrecy may be disclosed to a research organisation outside Sweden if the receiving organisation falls under the GDPR. If it would be possible to release the data to Swedish research database in corresponding cases, and if the research organisation is subject to secrecy rules corresponding to those that apply under the Public Access to Information and Secrecy Act and the Research Databases Act, the releasing authority may examine whether the data can be released.⁵⁵

SOU 2018:38 also proposes giving the Swedish Research Council (*Vetenskapsrådet*) the task of drafting a code of conduct for the processing of personal data in research databases⁵⁶ and following up the work of research databases in Sweden.

b. Modification to the processing authorisation procedure applying to research in the field of health

No major changes to the authorisation procedure in any of the on-going inquiries mentioned in I.B were identified for this report. The organisation coordinating the quality registers has, however, published guidelines with regards to the GDPR,⁵⁷ which mainly concern the administration of quality registers and less the authorisation procedure.

⁵³ See in Swedish SOU 2018:38 pp 245-246.

⁵⁴ Governmental Report 2017:50 p 38.

⁵⁵ Governmental Report SOU 2018:38 p 34

⁵⁶ Governmental Report SOU 2018:38 p 31

⁵⁷ Available in Swedish at <http://kvalitetsregister.se/drivaregister/juridikochregelverk.1946.html>



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How will the processing authorisation procedure (if any exists) be affected by the implementation of the GDPR? Can you describe any such change?

At this stage, no significant changes to the Ethical Review Act are proposed. The Research Data Inquiry Committee suggests minor changes to the Act regarding references to the GDPR instead of the current Personal Data Act.⁵⁸ According to the final report SOU 2018:38, however, the Committee finds that changes to the ethical review procedure should be investigated. The Committee believes that not all processing requires a full ethical review, as current ethical review requirements also cover processing of personal data that can generally be regarded as less of a risk for the individual.⁵⁹

Another inquiry, *SOU 2017:104 Etikprövning – en översyn av reglerna om forskning och hälso- och sjukvård*, has examined the Ethical Review Act from a more general perspective and has not focused on the GDPR. The inquiry suggests certain changes in order to make the Act clearer and easier to follow; for example, the inquiry proposes updating the basic definitions of “research” and “research principal” in order to clarify the scope of the act.⁶⁰ In addition, the inquiry suggests that retrospective ethical review should be possible in some cases; this would apply where a research activity in Sections 3–5 of the Ethical Review Act relates to health and medical services and a patient’s life or health would be threatened to await the ethical review. The new rules are suggested to enter into force on 1 January 2019. Again, the Government Bill has to be awaited in order to see if any significant changes to the proposal are made.

What about the right of the data subject and the obligations of the controller?

Article 89 (2) GDPR allows Member States to enact derogations from the rights referred to in Articles 15, 16, 18 and 21 subject to the conditions and safeguards referred to in Article 89 (1). The Research Data Inquiry Committee proposed in its earlier report certain restrictions in the new Research Data Act.

According to SOU 2017:50 the right to restriction of processing (Article 18 GDPR) “*shall not apply where the data subject contests the accuracy of the data during the verification period [...] if this means that the research cannot be carried out or would be crucially delayed or impeded. The same shall apply when the data subject has objected to processing, pending the verification whether the legitimate grounds of the controller override those of the data subject.*”⁶¹

The right to rectification (Article 16 GDPR) shall not apply to personal data that is only preserved to document and archive research that has already been completed (Section 13 of the new Research Data Act). The right to rectification shall otherwise apply without derogations. Section 13 is not part of the final proposal in SOU 2018:38.

The Research Data Inquiry Committee also proposes that individuals should be able to contest their personal data being processed for research purposes. If this option proves to be impossible or involves disproportionate effort, or

⁵⁸ See in Swedish SOU 2017:50 pp 47-48.

⁵⁹ SOU 2018:38 pp 28-29.

⁶⁰ SOU 2017:104 p 31.

⁶¹ SOU 2017:50 p 36.

if the purposes of the research cannot otherwise be attained, the data may nevertheless be processed (Section 9 of the new Act).⁶² Section 9 is not mentioned in the final proposal in SOU 2018:38.

The final report SOU 2018:38 does, however, stipulate technical and organisational security measures in Chapter 3 and introduces an obligation for the controller to assign resources for information security.

5. Further processing for research purposes under the GDPR

The notion of further processing under the GDPR:

The Research Data Inquiry Committee points out that the current Personal Data Act may need clarification in relation to further processing for research purposes. According to the Committee, it is not clear if a new legal basis is needed for further processing, particularly in cases where the data was originally gathered through consent.⁶³ It is currently unclear whether any changes will be made in this regard, however, as the Committee concludes that further processing for research purposes can be understood as compatible with the original processing.

A new controller, however, “must have their own legal basis for their processing for research purposes once the personal data has been transferred to them. This means that research actors that collect personal data for research purposes that was previously collected for other purposes, for example, by another agency, must cite a legal basis under Article 6(1) for the new processing. Such a legal basis may be research carried out in the public interest under Article 6(1)(e) GDPR.”⁶⁴

The Committee views that it is in line with Article 9 (2)(a) GDPR to process sensitive personal data for research purposes with consent as the legal basis if consent exists together with ethical approval in accordance with the Ethical Review Act.⁶⁵

How to measure the compatibility of purpose of the further processing:

Neither the general inquiry for a new Data Act (*Prop 2017/18:105, Ny dataskyddslag*) nor the Research Data Inquiry Committee discuss compatibility in detail. The Research Data Inquiry Committee does however consider that research is generally compatible with the original purpose.

⁶² SOU 2017:50 p 38.

⁶³ SOU 2017:50 pp 32-33.

⁶⁴ SOU 2017:50 p 33.

⁶⁵ SOU 2017:50 p 33.

The Research Data Inquiry Committee also discusses compatibility with regards to more specific laws, such as the LifeGene Act, and comes to the conclusion that only the purposes stated in the specific Act can be deemed compatible.⁶⁶

The particularities of scientific research: a presumption of purpose compatibility

The Committee interprets Article 6 (1) GDPR to mean that further processing for research purposes by the same data controller does not need a new legal basis. It is enough that the original data collection was based on a legal ground according to Article 6 (1).

When it comes to sharing personal data for research purposes with another data controller the “new” processing shall be considered compatible as long as the purpose is research. The “new” data controller, however, has to state a legal ground according to Article 6 (1) for the “new” processing. Such a legal ground can be public interest according to Article 6 (1) (e).⁶⁷

The Research Data Inquiry Committee proposes that further processing of personal data for research purposes by the same data controller shall be considered compatible with the original purpose even if the data was collected based on consent by the data subject.

If the original data collection was based on consent, further processing of personal data for research purposes should generally be covered by obtaining new consent, irrespective of whether this is carried out by the same or a new controller. This should apply irrespective of the wording of Article 5 (1)(b) second sentence if it is possible in practical terms and not inappropriate on ethical grounds. In other words, the Research Data Inquiry Committee proposes that further processing of personal data for research purposes should require asking for consent again, if the original processing was based on consent. This is irrelevant of whether the processing is carried out by the same data controller or a new data controller.⁶⁸

The data controller is, in all cases, advised to follow the Council of Europe Recommendation No. R (83)10.⁶⁹

Given the regime applied to further processing in the GDPR, can you describe the consequences, if any, in your national legal framework?

As most of the inquiries only reached the stage of Governmental Reports, the actual consequences are not clear at the moment. There is still a possibility that the Government Bills will introduce some changes, and as such the consequences are not easy to predict. However, the only substantial amendment currently proposed is to introduce a specific Research Act, meaning that the practical consequences are limited in nature. Further processing for

⁶⁶ SOU 2017:50 p 390.

⁶⁷ SOU 2017:50 pp 146-147.

⁶⁸ SOU 2017:50 pp 182-183.

⁶⁹ RECOMMENDATION No. R (83)10 OF THE COMMITTEE OF MINISTERS TO MEMBER STATES ON THE PROTECTION OF PERSONAL DATA USED FOR SCIENTIFIC RESEARCH AND STATISTICS' (Adopted by the Committee of Ministers on 23 September 1983 at the 362nd meeting of the Ministers' Deputies), https://search.coe.int/cm/Pages/result_details.aspx?ObjectID=09000016804bc647



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research purposes is considered within the scope of the new framework, as it is already today in the Personal Data Act.

Update August 2018: Though most of the general reports have now been enacted, e.g. the Data Protection Act was enacted in May, the more relevant legislation for this report – the Research Data Act – has not yet reached the government bill stage. It seems, however, that the changes will not be substantial, as the focus is on the ethical review procedure. These changes may facilitate access to research databases but also decrease the predictability of the conditions for the approval, as much discretion is left to the ethical vetting boards.

6. Health data sources for research purposes

a. Sources of data and their regulation

Does your national framework contain specific provisions for anonymised or pseudonymised health data?

According to Chapter 7 Section 8 Patient Data Act an individual's personal identity number (in Swedish *personnummer*) or name may only be used in the quality registers if coded personal data, i.e. pseudonymised data, is not sufficient for the purpose of the processing.

According to Chapter 4 Section 4 Biobank Act tissue samples that are shared shall be depersonalised⁷⁰ or coded. The code keys shall be stored with the healthcare provider that collected the data initially and that stores the tissue samples in a biobank. Code keys shall be stored securely. The usage of code keys can be viewed as an example of pseudonymisation.⁷¹

The Research Data Inquiry proposes a provision in the new Research Data Act stipulating that personal data must be pseudonymised or protected in an equivalent manner when processed for research purposes provided that the purpose can be attained by doing so.⁷²

What are the different sources of health data that can be used for research purposes?

- **DIRECT COLLECTION FROM PATIENTS:**

⁷⁰ The Swedish wording is *avidentifierade* which is not a synonym for anonymised.

⁷¹ Compare also SOU 2017:50 p 263.

⁷² SOU 2017:50 p 38 and SOU 2018:38 p 43 proposal for Chapter 5 Section 2 Research Data Act.



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Under the current legal framework: please explain the currently applying rules that a researcher, who intends to collect health data directly from individuals (e.g. via a survey, or by asking patients to wear a monitoring device, etc.), should follow.

The main applicable legislation in this case is the Ethical Review Act with the requirements of application for approval. In addition, all individuals must receive information regarding the research, and the type of data processing the research will involve, for a valid consent to be granted.

Depending on which data is being collected some of the other Acts mentioned in Chapter I.A. can be applicable as well, e.g. the Biobank Act.

Any processing of personal data has to follow the Personal Data Act. To the extent the research involves patient care, the Patient Data Act applies instead.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Based on the current on-going governmental inquiries no substantial changes are being proposed with regards to the GDPR. One of the main proposals in SOU 2017:50 is that research can be based on the legal grounds of public interest according to Article 6 (1)(e) GDPR and that the newly proposed Research Data Act should serve as the legal basis for both public and private research actors.⁷³ According Section 6 in the new Act (mentioned in SOU 2017:50), which refers to Article 6 (1)(e) GDPR, personal data can be processed for research purposes if the processing is necessary and proportional for conducting research of public interest. Research of public interest can be carried out by public authorities, municipalities, counties, other legal persons and individual companies. SOU 2018:38 proposes in Chapter 2 Section 3 that personal data may be processed in a research database if it was approved by ethical review and the research actor has secured financing for the database. The Act does not mention research, mainly focusing on rules for research databases rather than specific research projects.

Otherwise no changes in procedure are currently proposed, so focus lies still on the ethical review.

- **COLLECTION FROM HEALTH PROFESSIONALS AND HEALTH INSTITUTIONS**

Under the current legal framework: please explain the rules currently applying that a researcher, who intends to obtain health data from medical staff, hospitals, etc., should follow.

A variety of quality register exist today in Sweden⁷⁴ and the providers of these registers may share data provided certain conditions are fulfilled. In order to access data a researcher has to contact the register itself, the National

⁷³ SOU 2017:50 p 151.

⁷⁴ A full list is available in English at <http://kvalitetsregister.se/englishpages/findaregistry.2027.html>

Board of Health and Welfare (*Socialstyrelsen*) and apply for permission to conduct research with the Ethical Review Board.

A quick guide for researchers to quality registry data disclosure is available in English at <http://kvalitetsregister.se/englishpages/useregistrydatainyourresearch/quickguideforresearchers.2409.html>. A more detailed overview can be found in English at <http://kvalitetsregister.se/englishpages/useregistrydatainyourresearch/guidanceondisclosureofregistrydata.2410.html>.

In addition, biobank providers may share data from their biobanks according to the Biobank Act. The recommendation by Biobank Sweden for release of samples and personal data for research proposes the following requirements:

1. The research subject must have consented for the sample to be used for the purpose in question. For research, explicit and specific consent is required for the specific research study. The Ethics Review Board may allow exemptions from the information and consent requirement, however.
2. Enough material must be left for diagnosis and treatment.
3. Existing contracts and regulations for the biobank must be respected
4. The research study must have been approved by the Ethical Review Board. The approval includes use of samples as well as personal data.
5. If the release concerns an existing research related biobank, coordination with the researcher of the existing biobank is recommended.
6. Biobanks should be shared with other researchers in order to stimulate further cooperation.⁷⁵

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

None of the on-going inquiries (see I.B.) propose substantial changes in the existing procedure. The above mentioned Research Data Inquiry Committee proposes, however, in SOU 2018:38 that the ethical review procedures should be further investigated as not all processing of personal data necessarily requires a full ethical review.⁷⁶

- **PRIVATE DATABASES**

Under the current legal framework: please explain the rules currently applying for the setting up of and the use of a private database with health data for research purposes.

⁷⁵ Biobank Sweden, *Principer för tillgång till biobanksprov och personuppgifter för forskning*, 24 January 2018, <http://biobanksverige.se/wp-content/uploads/k1-principer-tillgang-till-biobanksprov-51.pdf>, p 15.

⁷⁶ See above p 15-16.



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From a Swedish point of view, there is no clear-cut distinction between private and public, but rather between quality registers and biobanks. Databases falling within the definition of a quality register can only be administered by public authorities, according to Chapter 7 Section 7 Patient Data Act. Biobanks, however, can be established by private entities. Creating a private database containing health data is not prohibited as such. An application is, however, necessary in accordance with the Ethical Review Act.

According to Chapter 3 Section 1 Biobank Act (Consent and Information) tissue samples may only be collected and stored in a biobank if the research subject has consented after receiving information on the aim and purpose of the biobank. Chapter 3 Section 5 further states that if research or clinical trials involves a new purpose the Ethical Review Board has to approve the new purpose and also decide the requirements for information and consent of the individual. This also reflects Section 15 of the Ethical Review Act.

If samples are released from a biobank (see above), the receiver of the samples becomes responsible for a secondary biobank which must not be shared with anybody else.⁷⁷ The only exception to this rule is Chapter 4 Section 5 Biobank Act which allows tissue samples to be sent to another healthcare provider for analysis and samples to be sent to another unit for research. In both cases samples may be sent abroad, though the specimens shall be coded at all times and destroyed if no longer needed for the original purpose.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The on-going inquiries do not suggest any substantial changes for the conditions applying to private databases. The SOU 2017:50 does, however, propose that personal data be pseudonymised or protected in an equivalent manner when processed for research purposes provided that the purpose can be attained by doing so (Section 8 of the new Research Data Act).

- **PUBLIC DATABASES**

Under the current legal framework: do public authorities make available health data for research purposes in your country and under what conditions?

As mentioned in I.A., quality registers have been established in Sweden for a time. There are around 100 quality registers, containing data on health problems, diagnoses, treatment and results.⁷⁸ Following an application to a provider of a specific register, an application to and vetting procedure by the Ethical Review Board and contact with the National Board of Health and Welfare (*Socialstyrelsen*)⁷⁹, researchers can receive access to this data.

Quality registers do not require consent of the patient, but are based on an opt-out model. Chapter 7 Section 3 Patient Data Act does, however, stipulate that the data subject has to be informed about the processing. Chapter 7

⁷⁷ Biobank Sweden, *Principer för tillgång till biobanksprov och personuppgifter för forskning*, 24 January 2018, <http://biobanksverige.se/wp-content/uploads/k1-principer-tillgang-till-biobanksprov-51.pdf>, at 14.

⁷⁸ A list is available in English at <http://www.kvalitetsregister.se/englishpages/findaregistry/allswedishqualityregistries.2028.html>

⁷⁹ A quick guide for researchers to quality registry data disclosure is available in English at <http://kvalitetsregister.se/englishpages/userregistrydatainyourresearch/quickguideforresearchers.2409.html>. A more detailed overview can be found in English at <http://kvalitetsregister.se/englishpages/userregistrydatainyourresearch/guidanceondisclosureofregistrydata.2410.html>.



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Section 2 Patient Data Act states that personal data may not be processed in a quality register if the individual opposes the processing. As only public authorities are allowed to administer quality registers, the data is protected by the Public Access to Information and Secrecy Act, as mentioned in II.C.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The on-going inquiries do not suggest any substantial changes to the rules applicable to the use of public databases. The Government Bill *Prop. 2017/18:171* proposes only small amendments in the wording of the provisions in Chapter 7 Section 8 Patient Data Act: sensitive personal data may be processed based on Article 9 (2) (h) GDPR under the condition that the requirement of confidentiality in Article 9 (3) is met. The changes have not been enacted yet, however.

In general, the proposed changes in the Government Bill are not substantial. The organisation coordinating all quality registers has, however, published guidelines on the GDPR implementation⁸⁰, specifically with regards to the obligations of the data controllers, and detailing the different requirements of the GDPR. The changes affect primarily the providers of quality registers in their daily processing and administering of the registers.

b. Application of the national framework to the AEGLE cases

In the AEGLE project, the “research objective is to establish the use of Big data analysis in the prediction of outcomes in three working scenarios: Chronic Lymphocytic Leukemia (CLL), Intensive Care Units and type 2 diabetes for the prediction of adverse outcomes. The research methodology is Big Data analysis to establish predictive values that may apply in three clinical scenarios and to see if this can be generalised to other healthcare disease models”.⁸¹

To achieve its objective, the AEGLE project must base its approach on the study, and thus the processing, of data concerning health. This section aims to address each of the three proposed AEGLE cases, and to determine the requirements in general terms for access and the processes relevant to data under the Directive (the current framework) and the GDPR.

1. Type 2 diabetes

The AEGLE project uses, after pseudonymisation, existing databases with health data collected from patients who expressed their consent to their data being used for research purposes.

⁸⁰ In Swedish at <http://www.kvalitetsregister.se/drivaregister/juridikochregelverk.1946.html>

⁸¹ AEGLE Grant Agreement, Annex 1, p. 83.

One of the Swedish quality registers contains health data on type 2 diabetes.⁸² The general rules of access to quality registers apply to access this data. A researcher needs to contact the registry itself, the National Board of Health and Welfare (*Socialstyrelsen*) and apply for permission to conduct research with the Ethical Review Board.⁸³ The application procedure for approval must be undertaken in accordance with the Ethical Review Act.

The application to the specific registry must be made in accordance with their own guidelines.⁸⁴ There is no legal right of access to registry data, even for researchers, rather access is dependent on approval from both the Ethical Review Board and the quality registry.

As such activity involves processing of sensitive data, the rules of the Personal Data Act apply. In addition, the Public Access to Information and Secrecy Act applies to the registers. In the event the researcher accessing the data is not a public authority and therefore not bound by the Public Access to Information and Secrecy Act, confidentiality clauses are required.

Following the enactment of the GDPR, the procedure as such will remain unchanged. However, it may be possible for private researchers to claim a public interest as a legal ground for processing data if the proposed Research Data Act is implemented in its current form. Pseudonymisation will be explicitly required according to Section 8 of the new Research Data Act. In addition, a data protection officer will be required according to Article 37 GDPR and the supervisory authority needs to be provided with this information.

2. Intensive Care Unit (ICU)

AEGLE uses data generated by ICU devices without collecting the patient's consent (after pseudonymisation).

The National Quality Registry for Intensive Care (SIR) contains data on diagnoses, interventions, inpatient care, patient-reported health effects, and follow-ups from intensive care units.⁸⁵ The same rules regarding access to quality registry data apply, as for type 2 diabetes above.

A researcher needs to contact the registry itself, the National Board of Health and Welfare (*Socialstyrelsen*) and apply for permission to conduct research with the Ethical Review Board.⁸⁶ The application procedure for approval must be undertaken in accordance with the Ethical Review Act.

⁸² See more in English at <http://www.kvalitetsregister.se/englishpages/findaregistry/registerarkivenglish/nationalqualityregistryfordiabetesndrwithswediabkids.2161.html> and the registry website <https://www.ndr.nu/#/english>

⁸³ See for an overview in English <http://www.kvalitetsregister.se/englishpages/useregistrydatainyourresearch/quickguideforresearchers.2409.html>

⁸⁴ The application for the diabetes quality registers is available in Swedish at https://www.ndr.nu/pdfs/ansokan_utlamnande_forskning.doc

⁸⁵ See an overview in English at <http://kvalitetsregister.se/englishpages/findaregistry/registerarkivenglish/nationalqualityregistryforintensivecaresir.2175.html> and the website of the registry <http://www.icuregswe.org/en/>

⁸⁶ See for an overview in English <http://www.kvalitetsregister.se/englishpages/useregistrydatainyourresearch/quickguideforresearchers.2409.html>



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The application to the specific registry must be made in accordance with their own guidelines.⁸⁷ There is no legal right of access to registry data, even for researchers, rather access is dependent on approval from both the Ethical Review Board and the quality registry.

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3. Chronic Lymphocytic Leukaemia (CLL)

The AEGLE project re-uses, after pseudonymisation, data coming from biobanks. In this instance, patients have given their informed consent for the samples and for the processing of their data. But this consent was given in general terms and not specifically for AEGLE.

The rules for biobanks are both established in the Biobank Act and the guidelines of a specific biobank. Biobank Sweden recommends for biobanks to be clear when collecting data to what extent future research projects are encompassed. For example, it recommends that consent for further research be limited to a particular type of illness and apply for a certain period of time. Depending on the phrasing of the original consent form, AEGLE research may or may not be encompassed. A new ethical vetting procedure is in any case required and the Ethical Review Board may decide that additional consent is required for the research to take place.

In general, access to biobank data requires⁸⁸

- approval from the Ethical Review Board
- the fulfilment of any conditions of the ethical approval
- consent and information provided to the patient
- established routines and responsibility for coding/pseudonymisation
- a valid contract with the biobank

⁸⁷ Application forms are available in Swedish at <http://www.icuregswe.org/sv/Om-SIR/FoU-ansokningar/>

⁸⁸ Information in Swedish available at <http://biobanksverige.se/forskning/tillgang-till-prov-for-forskning/>

There is also a relevant quality register in Sweden, the National Quality Registry for Leukaemia⁸⁹ which includes CLL. In this case, the same procedure applies as to any other quality register in Sweden,⁹⁰ see scenarios 1 and 2 above.

Note:

While AEGLE has to apply to the different registries for access to the data, it might be possible to file one application to the Ethical Review Board. This is dependent on the scope of the project and may be possible where the application concerns different parts of the same research project. Approval from the Ethical Review Board is in all cases required to then apply to the specific registries or biobanks, and is therefore the first recommended step.

⁸⁹ <http://www.kvalitetsregister.se/englishpages/findaregistry/registerarkivenglish/nationalqualityregistryforleukaemia.2116.html> and the registry's website in Swedish <https://www.cancercentrum.se/samverkan/cancerdiagnoser/blod-lymfom-myelom/>

⁹⁰ Some information in Swedish is available at <https://www.cancercentrum.se/samverkan/cancerdiagnoser/blod-lymfom-myelom/kronisk-lymfatisk-leukemi-kl/kvalitetsregister/>. The principles for access are available in Swedish at https://www.cancercentrum.se/globalassets/cancerdiagnoser/blod-lymfom-myelom/rcc-styrdok_hematologi_160311.pdf



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