

ETHICAL REVIEW, DATA PROTECTION AND BIOMEDICAL RESEARCH IN THE NORDIC COUNTRIES: A LEGAL PERSPECTIVE

POLICY PAPER 1/2017



NordForsk



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in the Nordic countries: A legal perspective**
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PREFACE

NordForsk is an organisation under the Nordic Council of Ministers that provides funding for and facilitates Nordic research and research infrastructure in all fields of research when this adds value to activities being conducted in the Nordic region. Priority is given to thorough analysis as a basis for funding research that is deemed to have considerable potential for knowledge-based progress in the long term.

Health and welfare research is an area with particular Nordic added value. There is great potential within this field to produce knowledge that can be used to the benefit of the Nordic welfare states. This new knowledge can be translated into practical solutions, for example, for prevention, intervention and medical treatment.

During the last few years, NordForsk has made targeted investments in facilitating utilisation of Nordic health data in research. The Nordic countries possess unique population-based registries used for administrative purposes and statistics as well as high-quality biobanks. The Nordic countries are thus in possession of very extended time series that can be used for research purposes. The shared practice of issuing personal identification numbers to each citizen also gives these countries a superlative basis for carrying out longitudinal research and combining register data - across borders as well.

The potential for research based on Nordic data sets is evident, and there are many advantages to opening the door to research that could be conducted across the entire Nordic region. However, existing hurdles and bottlenecks, including legal ones, make it difficult to gain access to and share health data, and thus pose obstacles to its full exploitation.

This report has been commissioned by NordForsk in order to give the legal perspective on collection and re-use of health-related personal data in medical research in the Nordic countries. The report also takes a look at how ethical review is integrated in the regulatory frameworks, including in the European general data protection regulation that will come into force May 2018.

NordForsk would like to offer its sincere thanks to Dr Marjut Salokannel, legal consultant who has written this report.

Oslo, February 2017



Gunnel Gustafsson
Director of NordForsk

EXECUTIVE SUMMARY





COPENHAGEN, DENMARK
Photo: William Perugini/Shutterstock

EXECUTIVE SUMMARY

Purpose of the study

The purpose of this report is to give an overview of the existing legislation in the Nordic countries with regard to regulating the collection and re-use of health-related personal data in medical research, in particular from the point of view of how ethical review is integrated in the regulatory framework. The ethical review system in connection with clinical trials on medicinal products is discussed to the extent it refers to the application of the General Data Protection Regulation with regard to the further processing of clinical trials data. Otherwise, ethical review as required by the Clinical Trials Regulations has been analysed comprehensively in a separate report.¹

The report will analyse the applicable laws to the processing of sensitive health data for scientific research purposes for each of the Nordic countries in the following manner: First the report will look at the [primary processing of sensitive data](#), which, in the context of this report, refers to collecting data directly from the research subject either by consent or based on law. In legal terms this encompasses the processing of personal data which is subject to medical research laws and/or laws on ethical review of health research projects.

Secondly, the report will analyse, for each country, the different types of re-uses of the data that has already been collected (hereafter [secondary use of health data](#)) and whether ethical review is required by law in these cases.

The study concludes by analysing the impact of the newly adopted EU General Data Protection Regulation (hereafter the GDPR) from the perspective of harmonising ethical review practices in the Nordic countries. It is not possible to give a comprehensive picture of the impact of the GDPR on health research in the Nordic countries within the limits of this study, but it should be carried out separately.

New opportunities for the utilisation of health data

The spectrum of biomedical research is currently in a state of rapid change. New technologies have brought about new ways of utilising health-related data and permit matching data from different sources on a global scale in ways that were not conceivable a few decades ago. This will bring about new medicines, new methods of treatment and, hopefully, will increase the well-being of citizens around the globe. Some of the new ways of collecting health-related personal data have not always been welcome or even known to the persons concerned. This is a particularly relevant question in the Big Data environment, in which data from different internet-based sources are matched with personal data from other sources.

I wish to thank Professor Juni Palmgren, Professor Mika Scheinin, Senior Legal Adviser Ragnhild Angell Host and Senior Adviser Maria Nilsson for their valuable comments on the previous versions of this report. I am, of course, solely responsible for the content of the report.
The report has been updated until June 2016.

¹ Nordforsk – Nordic Trial Alliance Report on the Ethical Review Process for Clinical Trials in the Nordic Countries, 2016.

Common EU Regulatory framework to assure free movement of personal data within the EU

The regulatory environment with regard to utilising health-related personal data is currently also changing to catch up with the new ways of data processing. The EU has just approved the GDPR², which is the most comprehensive data protection legislative framework in the world. It will be applied as law in all the Member States and the countries of the EEA as of 25 May 2018. The impact of the GDPR is worldwide, since it covers most data processing services and data processing operations having EU-based data processors, or that target or involve EU citizens.

According to the GDPR, [the free movement of personal data within the Union shall be neither restricted nor prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data](#). (Art. 1.3) Moreover, with regard to [scientific research any national regulation should take into account the EU's objective to achieve the European Research Area](#) as stated in Article 179.1, Treaty on the Functioning of the European Union (TFEU).³

Furthermore, according to the TFEU, the Union shall support researchers to cooperate freely across borders and enable undertakings to exploit the internal market potential to the full, in particular through the opening up of national public contracts, the definition of common standards and the removal of legal and fiscal obstacles to that cooperation. (Art. 179.2, TU)

The purpose of this study is to give an overview of the current state of law relating to biomedical research in the Nordic countries. This study was commissioned for the purpose of analysing the role of ethical review in such research, with the exclusion of clinical trials, which explains the emphasis on ethical review in this study. The GDPR was adopted when this study was already in its concluding phase and it will be discussed mainly insofar as it has an impact on the role of ethical review in biomedical research within the EU. However, a general overview of the specific research-related provisions is also given.

Results of the study

In research utilising sensitive personal data the legal situation with regard to ethical review differs from one Nordic country to another. In Denmark and Norway the law is to a large extent similar. For research which is subject to health research laws, including research using biological materials, ethical review is obligatory. In addition, ethical review is required in Denmark for the use of patient records for research purposes. The Danish Health Authority may give permission to utilise patient records for a concrete biomedical research project of significant societal importance, which is not subject to the law on research ethics review of health research projects.

2 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 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. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2016:119:TOC>

3 The Union shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapters of the Treaties. Article 179.1 TFEU.

Sweden has a comprehensive law-based ethical review system regarding all research conducted with sensitive personal data regardless of whether the data is collected by consent or not. In Sweden this applies to both primary and secondary use of sensitive personal data. Iceland also has a comprehensive ethical review system covering all types of health research projects and storing of health-related data in health databases.

Denmark's recent legislation also provides for a coherent system for regulating the primary collection and use of health data and secondary uses of health data for scientific research purposes with ethical review well integrated in the system. Finland and Norway have statutory ethical review mainly with respect to medical research, which is subject to medical research laws. In practice, this relates to research involving either physiological or psychological intervention with research subjects. However, the relevant laws are also changing in Finland and Norway.

In Denmark and Norway, authorisation from the data protection authority replaces to a large extent ethical review with regard to secondary processing of health data for research purposes. In Finland, research permission from the home institution is regarded as sufficient and it does, in most cases, include an ethical review. Notification to the data protection authority is also called for.

The primary use of health data which requires informed consent from the data subject relates, when given in accordance with the data protection law, to the processing of personal data related to consent. Consent given in accordance with the EU clinical trials regulation relates to the participation in the clinical trial and to the use of personal data arising out of the clinical trial. Matching this data with other personal data, such as patient records or register-based data, requires separate consent from the data subject. (Art. 28.2 of the EU Clinical Trials Regulation⁴) This distinction has to be kept in mind when analysing the Nordic health research laws, because even if the Clinical Trials Regulation as such is not comprehensively discussed in this report, many provisions relating to ethical review are regulated by health research laws which also regulate clinical trials.

The EU General Data Protection Regulation provides a detailed set of rules with regard to consent for the processing of personal data. However, in respect to the processing of personal data for scientific research purposes there is more room for national flexibility. With regard to consent for the processing of health-related data, this flexibility relates to the possibility left to national legislators to allow consent to relate to certain areas of scientific research when in keeping with the recognised ethical standards for scientific research. The data subject must also have the possibility to give consent only for certain areas of research or part of research projects to the extent allowed by the intended purpose. The consents must be in compliance with the rules of the GDPR relating to consent when the Regulation enters into force in May 2018.

Using personal data included in public population-based registers for scientific research does not require consent in any of the Nordic countries or according to the EU General Data Protection Regulation. In Sweden ethical review is required. In other Nordic countries notification to and authorisation from the data protection authority are sufficient. In Finland a notification alone is sufficient. However, when these data are matched with personal data that have been acquired by consent, such as data from a clinical trial, the initial consent has to include permission to match consented personal data to register-based personal data. Such matching of register-based data with data acquired by consent also requires an ethical review in Denmark.

⁴ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance.

Local processing requirements as an impediment to Nordic research cooperation

Perhaps the most difficult obstacle to Nordic research cooperation relates to the current unclear situation as to the interpretation of national access to official documents and secrecy legislation in a cross-border setting. Similar problems are encountered with the strict interpretation of secrecy provisions in the national statistics acts, which have made it very complicated to have multi-country-based research projects using national statistics microdata.

The Swedish legislation on ethical review has also complicated the cross-border delivery of research data. It seems that it in practice is impossible to obtain Swedish register data for use in a research project conducted in another Nordic country because the required ethical review is only available for research being done in Sweden. Denmark also prefers a national affiliation for cross-border research projects and it offers a secure online access to its register data to researchers in other EEA -countries via a national research organization.

Some of the answers to these questions may come from the EU level in connection with the possible implementation guidelines for the GDPR.

1. FUNDAMENTAL RIGHTS AS THE BASIS FOR ETHICAL MEDICAL RESEARCH





HELSINKI, FINLAND

Photo: Rūta Saulyte-Laurinavičienė/Shutterstock

1. FUNDAMENTAL RIGHTS AS THE BASIS FOR ETHICAL MEDICAL RESEARCH

The Council of Europe Convention on Human Rights and Biomedicine (4 April 1997, ETS 164) confirms at the international level the importance of safeguarding the fundamental human rights of all people in relation to the application of biomedical research. Its stated purpose is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. (Art. 1) The Convention is based on the idea that the interests of human beings must always come before the interests of science and society. The Convention forms a general framework for bioethics and medical research, including requirements for consent and rights to private life and information.

The Convention was later complemented with various additional protocols. The most important of these for research is the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (25.1.2005, no.195). The Protocol calls for an obligatory ethical review for research projects on human subjects as well for a free, express, specific and documented informed consent from the research subject as a requisite for participation in a research project.

In addition, Recommendation Rec (2006)4 of the Committee of Ministers to member states on research on biological materials of human origin was adopted in March 2006. This Recommendation was updated in May 2016 (CM/Rec (2016)6) in order to take into account the opportunities and risks brought by new technologies for biomedical research. The Recommendation highlights the international and transdisciplinary nature of research as reflected in the establishment of international research infrastructures that pool and share samples and data across national borders, as well as the importance of interoperability of research infrastructures. It emphasises that every person has the right to agree or refuse to contribute to biomedical research and that no one should be forced to contribute to it. It also calls for fair access for researchers to collections of biological materials.

According to the accompanying guidelines, research projects using human biological materials should be subject to appropriate independent scientific and ethical review. Any information of a personal nature collected at the time of removal, storage or use of biological materials, or obtained through research, should be considered as confidential and treated according to the rules relating to the protection of private life. Research on biological materials should only be undertaken if it is within the scope of the consent given by the person concerned. Prior to consent to or authorisation for the storage of the material for future research use, the person concerned should be provided with comprehensible information that is as precise as possible with regard to the future research uses, conditions of storage and other relevant conditions governing the use of the materials.

Biological materials should only be removed for storage for future research with the prior, free, express and documented consent of the person concerned. The consent should be specific to the intervention carried out to remove the materials and it should be as precise as possible with regard to the envisaged research use. The guidelines also provide for the conditions in which research may be undertaken without an explicit consent from the person concerned.

Any use of biological materials in an identifiable form should be justified in advance in the research protocol. Non-identifiable biological materials may be used in a research project provided that such use does not violate any restrictions defined by the person concerned before the materials have been rendered non-identifiable and subject to authorisation provided for by law.

The transfer of biological materials is only possible if an appropriate level of protection is either ensured by the law of recipient State or by legally binding and enforceable instruments adopted and implemented by the parties. A documented agreement between the sender of the biological materials and the recipient should be signed. Appropriate consent or authorisation, including, where appropriate, any relevant restriction defined by the person from whom the biological matter originates, should be included in the agreement.

The *Declaration of Helsinki* of the World Medical Association⁵ has traditionally been regarded as providing the basis for the ethical principles to be applied to medical research involving human subjects, including research on identifiable human material and data. Just like the Council of Europe Oviedo Convention, the Declaration recognises that even if the purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

According to the Declaration, it is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy and confidentiality of personal information of research subjects. In their research physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. According to the Declaration, no national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects as required by the Declaration.

While the Declaration of Helsinki is not legally binding, it is generally accepted and taken as providing the ethical bases for medical research in the world. In addition to the Council of Europe Convention in the EU, the foremost legally binding basic instruments are the Council of Europe Convention 108 (Convention for the protection of individuals with regard to automatic processing of personal data 1.10.1985) and the EU Charter on Fundamental rights, which includes the basic legal principles to be applied also to medical research.⁶

Of the two the Charter on Fundamental Rights bears direct effect for our subject matter. The principle of free and informed consent included in the Helsinki Declaration is also set out in the Charter. [The EU Charter requires that any intervention in the field of biology and medicine cannot be performed without free and informed consent of the person concerned](#) according to the procedures laid down in law. The same article also [prohibits the making of the human body and its parts as such a source of financial gain](#). (Art. 3) This principle has also been reiterated in Recital 27 of the EU Clinical Trials Regulation.

Furthermore, the Charter confirms, for the first time that [the right to data protection is an independent fundamental right](#). (Art. 8) It states that everyone has the right to the protection of personal data concerning him or herself. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or herself, and the right to have it rectified.

Based on this, and already before, the EU has adopted internal legislation for the protection of the rights of citizens with regard to the processing of their personal data: first, the European data protection (Directive 95/46/EC) and now the European General Data Protection Regulation establish the basis for the processing of all personal data within the EU and the wider European Economic Area. In addition, the EU Clinical Trials Regulation establishes the basis for the processing of health-related data in scientific research.

⁵ WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, available at <http://www.wma.net/en/30publications/10policies/b3/>.

⁶ Charter of Fundamental Rights of the European Union (2000/C 364/01), available at http://www.europarl.europa.eu/charter/pdf/text_en.pdf

2. LEGAL SITUATION IN THE INDIVIDUAL NORDIC COUNTRIES WITH REGARD TO ETHICAL REVIEW AND BIOMEDICAL RESEARCH





STOCKHOLM, SWEDEN

Photo: Vereshchagin Dmitry/Shutterstock

2. LEGAL SITUATION IN THE INDIVIDUAL NORDIC COUNTRIES WITH REGARD TO ETHICAL REVIEW AND BIOMEDICAL RESEARCH

DENMARK

1. Primary collection and the processing of health data for scientific research

1.1. Ethical review

In Denmark primary processing of health data is governed by the *Act on Research Ethics Review of Health Research Projects* (no. 593, 14 June 2011), by the *Health Act (Sundhedsloven no. 1202, 14 November 2014)* and, in a complementary manner, by *the data protection law (Personal Data Act 429/2000)*. [When personal data are collected on the basis of consent for a particular health research project it is subject to statutory ethical review according to the Research Ethics Review of the Health Research Projects law](#), which lays down the legal framework for the research ethics evaluation of health research projects by ethical review committees.

For the purposes of ethical review there are one national research ethics committee and 11 regional committees. The Danish National Committee on Health Research Ethics coordinates the work of regional committees. (Part 7 of the Act on Research Ethics Review of Health Research Projects) The overall supervision of ethical review relating to health research is carried out by the *National Committee on Health Research Ethics*. The composition of ethics review committees and requirements for ethical review are provided in the Research Ethics Review Law.

In principle, [all health research projects must be notified to the ethical committee system and are subject to ethical approval](#). Health research projects are defined in the law as comprising, i.a.:

1. trials involving liveborn human individuals;
2. human gametes intended for fertilisation, fertilised human eggs, embryonic cells and embryos, tissue, cells, genetic material from humans, embryos, etc. or deceased persons;
3. clinical trials of medicines in humans and clinical trials of medical devices;
4. research involving human biological materials.

Notification of questionnaire surveys and medical database research projects to the system of research ethics committees is only required if the project involves human biological material.

Health research projects that solely involve anonymous human biological material collected in accordance with legislation at the site of collection need only be notified to the system of research ethics committees if the research project is regulated under Section 25 in the act on artificial insemination in connection with medical treatment, diagnostics and research.

Trials involving cell lines which originate from a trial regarding the collection of cells or tissue, and which have obtained the required permission, need only be notified if the trial concerns the use of fertilised eggs, stem cells and stem cell lines from these. (cf. Sections 25 and 27 (2) of the act on artificial insemination in connection with medical treatment, diagnostics and research, etc.) The Minister for the Interior and Health may lay down further rules on exemption from the notification obligation with regard to trials involving cell lines and similar biological materials. Following a recommendation from the national committee, the Minister for the Interior and Health may, furthermore, lay down rules on notification obligations for further defined new fields of research, which would otherwise be exempt from the notification obligation.

1.2. Informed consent

Informed consent is defined in the law as a decision to participate in a health research project which has been communicated in writing duly dated and signed, or has been communicated electronically with the use of a digital signature, and which has been taken freely by an individual able to give consent who has received adequate information on the project's nature, significance, implications and risks as well as adequate documentation. (Sect.2.1(10), Health Res. Rev. Act)

The law further clarifies that consent includes access to the communication and processing of required information on the trial subject's health, other wholly personal matters and other confidential information as part of own control of the research project, including quality control and monitoring which a sponsor or a possible monitor is under obligation to undertake. Consent may be withdrawn at any time without this being detrimental to the trial subject.

Consent by proxy may be given in situations when the research subject is a minor, under guardianship or an incapacitated adult.

Same requirements for consent apply also to the removal of tissue and other biological material in connection with concrete research projects with a view to storage in a research biobank. (Sect. 6, Health Res. Rev. Act)

Unless consent requirements follow from other legislation, the Minister for the Interior and Health may lay down further rules for the obtaining of informed consent or proxy consent for use in connection with notifiable health research projects that do not involve trial subjects. (Sect. 7, Health Res. Rev. Act)

Database research projects

An ethical committee may grant exemption from the requirement of consent or proxy consent if a notifiable database research project does not involve any health risks and if under the given conditions the research project can not otherwise put a strain on the trial subject. This also applies if it would be impossible or disproportionately difficult to obtain informed consent or proxy consent, respectively. (Sect. 10)

Acute situations

An ethical committee may allow a health research project that does not concern a clinical trial of medicines to be undertaken without prior consent if the nature of the research project is such that it can only be undertaken in acute situations in which the trial subject is not able to give informed consent and when it is not possible to obtain proxy consent, provided that:

1. participation in the trial may improve the person's health in the long term, or
2. the trial may improve the condition of other patients with the same disease as the trial subject and participation in the trial involves only minimal strain and risk for the trial subject.

Following such a trial, the investigator must seek to obtain informed consent or proxy consent as soon as possible. (Sect. 11)

When a private research project is subject to the Research Ethics Review of Health Research Projects Act, the approval of the ethical committee is sufficient and the research project does not have to acquire permission from the Data Protection Authority.

Amendments to the health research project

Significant amendments to the health research project must be submitted to the ethical committee for review purposes.

2. Secondary use of health data

Secondary use of health-related data is regulated in Denmark partly by the data protection law and partly by the *Research Ethics Review of Health Research Projects and Health Act (Sundhedsloven no. 1202, 14 November 2014)*. This part of the secondary use of health data, which is primarily regulated under data protection law, does not require obligatory ethical review in Denmark, but [it requires notification to and authorisation from the Danish data protection authority](#). In the following we shall analyse in more detail the different types of research using health-related data and relevant regulation in the Danish legal system. In addition to the above laws the use of health records and biological materials for research purposes is also regulated under the Health Care Act (Sundhedsloven no. 1202, 14 November 2014).

2.1 Processing sensitive personal data without consent

The general rule under the personal data act relating to the processing of already existing health data and other sensitive data for research purposes is that they may be processed [without consent of the data subject](#) presupposing that the processing is carried out

1. for statistical or scientific studies of significant public importance, and
2. the processing is necessary for carrying out these studies.

This [requires a notification to and prior authorisation from the Danish data protection supervisor](#). The data processed may [be further processed for scientific or statistical studies only](#). Handing over data to third parties also requires [a prior authorisation from the data protection supervisor](#). (Sect. 10 PDA)

In practice this means that the use of national population-based health data registers from The Danish Health Data Authority (*Sundhedsdatastyrelsen*)⁷ is contingent on the research project satisfying the requirements set out in the data protection law as being of significant public importance and that the processing is necessary for carrying out the studies. Projects must be notified to the Danish data protection authority, which will set the terms of delivering data for the particular project. Depending on the project, the person notifying the data protection supervisor is either the person responsible for the research project (classical research service) or The Danish Health Data Authority (Research Machine).⁸

⁷ See more closely regarding the new authority: sundhedsdatastyrelsen.dk. Before November 2015 national population-based health data registers were hosted by Statens Serum Institut (SSI).

⁸ <http://sundhedsdatastyrelsen.dk/da/forskertjeneste>

Notification to and prior approval from the data protection authority is required also when the processing of sensitive personal data for research purposes is carried out in the private sector. This applies for all traditional register-based research, interviews and surveys and other types of research **not utilising biological materials**.

Private sector health research projects that are subject to scientific ethical review in terms of the Research Ethics Review of Health Research Projects Act do not need to be notified to the data protection supervisor. The same applies to clinical studies of medicines which are subject to medicines legislation. This means that the research projects that involve the processing of biological materials are subject only to scientific ethical review.⁹ In other words, the processing of sensitive personal data in a health research project is exempted from the notification requirement if the project is subject to the *Act on Research Ethics Review of Health Research Projects* and it has authorisation from the relevant ethical committee.¹⁰

Exemption from the notification requirement to the data protection supervisor relates only to private data controllers. **Public research projects will still have to be notified to the data protection supervisor.** Moreover, a prior authorisation from the data protection authority is called for if personal data are handed over to a third party from the project.

2.2 Patient records

According to the Health Care Act (*Sundhedsloven* no. 1202, 14 November 2014), the use of patient records or other information relating to individual health status as well as other similar information contained in patient records can be given to a researcher for a concrete biomedical research project under the condition that permission has been required from a regional ethics committee. (Sect. 46, *Sundhedsloven*) This means that ethical review is obligatory when information from patient records is used for a concrete biomedical research project under the *Research Ethics Review of Health Research Projects and Health Act*.

If the research project is not covered by the law on research ethics review of health research projects, the data can still be used for a concrete biomedical research project of significant societal importance if approved by the Patient safety board. The health data from patient records can only be further used for research and statistical purposes. It may not be disclosed in any form that could be traced back to an individual person. (Sect. 46.2, *Sundhedsloven*)

Research projects which use only register-based data without any biological materials are not subject to ethical review but they may need permission from the Danish Health Authority (*Sundhedsstyrelsen*) if they use patient records or registers hosted by the Health Authority. These projects also must be notified to and authorised by the Danish data protection authority.

2.3 Research and care biobanks

Patients can donate biological material for their own care-related purposes and this material is stored in a biobank. **Patients can prohibit the use of the biological material for other than care-related purposes.** Such prohibition is **registered** in the register relating to the use of biological materials (*Vaevsanvendelsesregisteret*) (Sect. 29.1, *Sundhedsloven*).

Biological material can be handed over for scientific research purposes for a concrete scientific biomedical research project after permission has been given by the ethical committee according to the Research Ethics Review of Health Research Projects Act unless the patient has registered a prohibition relating to the use of the material for non-patient care purposes, such as research. (Sect. 32, and 29.1 for prohibition, *Sundhedsloven*)

⁹ <http://www.datatilsynet.dk/erhverv/forskere-og-medicinalfirmaer/standard-terms-for-research-projects/>

¹⁰ Exempt from notification in the private sector are the following:

- kliniske forsøg med lægemidler omfattet af lov om lægemidler,
- kliniske afprøvninger af medicinsk udstyr omfattet af lov om medicinsk udstyr,
- sundhedsvidenskabelige forskningsprojekter omfattet af lov om videnskabetisk behandling af sundhedsvidenskabelige forskningsprojekter
- pligtmæssig sikkerhedsovervågning af lægemidler og medicinsk udstyr efter lov om lægemidler eller lov om medicinsk udstyr
- studerendes projekt- og specialeopgaver mv. som led i deres erhvervsakademi-, professionsbachelor-, bachelor- eller kandidatuddannelse eller uddannelse på tilsvarende niveau, når behandlingen sker med udtrykkeligt samtykke fra den registrerede.

<https://www.datatilsynet.dk/blanketter/privat-sektor/forskning-og-statistik/forskning-og-statistik-vejledning/>

A research biobank is defined in the law as a structured collection of human biological material that is kept with a view to a specific health research project, and which may be accessed according to defined criteria and where information bound in the biological material may be traced to individuals. (Sect. 13, Health Res. Rev. Act)

Research utilising human biological materials is subject to ethical review according to the law and the same requirements for consent apply when the research involves the removal of tissue and other biological material in connection with concrete research projects with a view to storage in a research biobank.

The processing of personal data related to biological materials stored in biobanks is regulated under [data protection law](#). This means that [all collections of human data and biological materials must be notified to and approved by the Danish data protection authority before any processing of the data can take place](#).

Patients can also demand that the biological material shall be destroyed under the condition set forth in the Health Act. (Sect. 33) The Health Act also provides for specific rules for contracts relating to handing over biological material to private enterprises. (Sect. 35)

2.4 Local processing requirements with respect to the processing of data from public population-based registers

According to the law relating to central population-based registers (*Lov om det centrale personregister*, no. 1134, 20 November 2006), local municipal authorities and the Ministry of Social Affairs and the Interior may give out personal information for statistical and research purposes (§35) from their central population-based registers presupposing that the receiver of the information is entitled to process this particular personal data according to the Personal Data Act.

The Ministry of Social Affairs and the Interior may also grant a digitised search and retrieval access to their online central population-based registers for statistical and research uses presupposing that the persons using the data are entitled to use it according to the Personal Data Act. When granting access, the Ministry sets the terms of access, including the relevant data security measures and payment. (§36)

This means that access to the central population-based registers takes place in a protected online environment of the register-hosting organisation. The law does not appear to prevent access from also being granted for research purposes to a non-Danish EU-based institution, or rather, to a user from such an institution, via a remote access portal connected to the Danish register-hosting institution if this is technologically possible. This presupposes that the user satisfies the requirements of the Danish data protection law to process the personal information in question.

The cross-border use of Danish register-based data from the Danish Health Data Authority (*sundhedsdatastyrelsen*) always requires an affiliation with the Danish research institution for the actual delivery of the data. In this case, the data are delivered to the Danish research organisation and the foreign researcher can gain access to the data through that organisation.

Access to or transfer of any Danish data to non-EU or EEA countries requires separate permission from the Danish data protection authority. With regard to health information the Danish Ministry of Interior and Health gives more specific regulations in this respect. (*Sundhedsloven*, §49)

FINLAND

1. Primary processing of health data for scientific research

1.1 Ethical review

In Finland the National Committee on Medical Research Ethics (TUKIJA) acts as an advisory body on research ethics and as the competent ethics committee for clinical trials of medicinal products. TUKIJA may assign an individual clinical trial for assessment by a regional ethics committee. Each hospital district, which has an educational organization giving university level medical education, has, at minimum one regional ethics committee. The biggest hospital district, Helsinki and Uusimaa Hospital District, has four. Altogether there are nine regional ethical committees (Ch. 4, the Medical Research Act (794/2010)).

There is no appeal process in ethical approval in Finland but the applicant may send a modified application for re-evaluation to the regional ethics committee. In this case, the regional ethics committee shall ask for an advisory opinion from the national ethics committee TUKIJA. (§3.4, Medical Research Act)

1.2. Primary processing of health data

In Finland the primary processing of health data is governed by the Personal Data Act (PDA) (523/1999) and the Medical Research Act. According to the Medical Research Act, an [obligatory ethical review is required with respect to all research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of health, the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of diseases in general. The law covers both physical and psychological intervention on humans.](#)

The law provides for detail regulation with regard to consenting for clinical research and the possibilities for derogating from such consent. The research subject is also provided for a right to withdraw the consent and the law provides for rules for the use of personal data of the research subject after the consent has been withdrawn. (Sect. 6 and 6a)

2. Secondary processing of health data in Finland

2.1. General principles applicable to the processing of personal data for scientific use without consent

Non-interventional research on humans, such as register-based research and other statistical research, does not fall under the Medical Research Act and does not require an ethical review by law in Finland. However, [the processing of personal data without consent for research purposes requires that the general requisites of data protection are fulfilled and that the specific conditions given in the law are satisfied.](#) This means that [the processor must have a legitimate basis](#) to process personal data for research purposes. The legitimate purposes can be given in sector-specific legislation, in which case the data protection law is applied in a complementary manner. In the absence of sector-specific legislation the requisites of the data protection law must be satisfied.¹¹

According to the PDA (§14), it is possible to use personal data for research purposes without the consent of the data subject, or based on other factors set out in the law, under the following conditions:

The research cannot be carried out without identifiable personal data and it is difficult to obtain the consent of data subjects due to the large number of data subjects or because the information is so old that it is difficult to track down the data subjects.

¹¹ For sensitive personal information the basis for processing data are given in cf. Sect. 12.1(5) and (6), PDA.

The use of the register of personal data is based on a research plan and there is a Principal Investigator or a research group that is in charge of the research project. The data used in the research must be linked to the research plan and the use of personal data must be justified in terms of the research project. The register of personal data must be used in a manner that prevents the disclosure of the identity of the research subjects to outsiders, and data may be handed over only for historical or scientific research. The register must be destroyed or archived or the data must be anonymised when it is no longer necessary to have the data in identifiable form or when it is no longer necessary to keep the data for verifying the research results. (Section 14, PDA)

These principles are applied cumulatively, so that [all of them must be satisfied in order for the processing of personal data for research purposes to be lawful](#). These principles must also be applied in a complementary manner when personal information is processed on the basis of the consent of the data subject. The same principles apply when the processing of personal data is based on sector-specific legislation. (Section 14.2, PDA) As far as we can see, [no ethical review is required by the law. The sector-specific laws do, however, in most cases require notification to the data protection authority](#). This does not, however, imply authorisation, but merely gives the data protection authority the possibility to intervene if necessary.

2.2 Official public registers

Research utilising public population-based official registers is governed by the *Act on the Openness of Government Activities* (621/1999), (hereafter The Finnish FoIA), and by any applicable register-specific law. [Obligatory ethical review is not required for research using official registers](#) but an institutional ethical review may be when the data request relates to personal information which is deemed [secret](#) under the Finnish FoIA. In such cases, the [register-hosting authority has the obligation to determine whether there is a basis for handing over data for research purposes in each individual case](#).

If the permission for receiving the information is required from several registers hosted by different public bodies in the area of health and social welfare, the permission is applied from and granted by the Ministry of Social and Health Affairs.

In addition, the register-specific laws require [notification to the data protection authority](#) when personal data are released for research purposes from the register. This is the case, for example, in respect of handing over data for research purposes from national population-based health registers. The competent authority for granting permission in this case is the National Institute for Health and Welfare.¹² Furthermore, when secret information is released from a public register for research purposes, the relevant provisions of the data protection law have to be taken into account in a complementary manner.

When it is a question of releasing data held by a public authority that is considered secret in terms of the Finnish FoIA, the data may only be released for research purposes under the condition that this does not infringe upon the right of protection for which the secrecy provision is enacted. This will be decided on a case-by-case basis, and the interests of scientific research must also be taken into consideration when granting permission. (Section 28, FoIA) This provision applies to all handing over of health or social security-related data from public registers. [The data subject may not object to the research uses of any of these secondary uses of data](#). For patient records the law differs to some extent (see below).

The general rules relating to handing over personal data from public registers under the Finnish FoIA must also be abided by when it is a question of data considered secret in terms of the Act. According to the Finnish FoIA, access may be granted to a public register if the person requesting access has the right to record and use the data in accordance with the legislation on the protection of personal data, unless otherwise stipulated in other legislation. (Section 16.3, FoIA) In practice, this means that personal data can be handed over for research purposes if the receiver of the data satisfies the requirements of the PDA in relation to processing data for research purposes without the consent of the data subjects. This means that [the receiver of the data must have a legal basis to process the data and the processing must take place under the conditions given in Sect. 14 of the Personal Data Act](#) (see above at 2.1).

¹² Act relating to national health registers (556/89), §4.

However, if the data held by a public authority has been obtained by consent from the data subject, the further use of such data is subject to this consent. Matching it to other data thus requires separate consent if not covered by the original consent. (Sect. 28, FoIA).

2.3 Patient records

The Health Service Act provides for the inclusion of care related patient data in the hospital district patient registry. Other service providers within the same hospital district may use the patient information for their care related purposes unless the patient has prohibited this. The patient must be informed for the possibility to prohibit the use of her data by other service providers. The fact that the patient has been informed and the eventual individual prohibitions must be registered in the patient record. The patient may prohibit the use of data or withdraw the prohibition at any time. (Sect. 9, Health Service Act 1326/2010)

The further details for processing personal data in patient registry are given in the law relating to electronic processing of social and health care customer data. (159/2007) this law applies to all medical records stored in the national centralised computerised system. The law also provides patients with the possibility to either consent or prohibit the handing over of their personal data to other social and health care service providers or for scientific research. (§10, 1227/2010)

The use of patient records for research purposes is subject to the law relating to patient's status and rights (785/1992), which in turn refers to the general rules relating to handing over personal data from public registers under the Finnish Act on the Openness of Government Activities. As we have seen, this means that they are secret, but access to them for research purposes may be granted in an individual case if this is not regarded as detrimental to the rights of the patient and the general conditions for processing data for research purposes under Finnish data protection act are satisfied. In addition, the Finnish Institute of Health and Welfare may grant permission for accessing patient records when they are required from more than one public or private health care organisation. There is no statutory ethical review in this case. (Law relating to patient's status and rights §13.5, 795/2010)

2.4 Biobanks

According to the Finnish Biobank Act (688/2012), the inclusion of biological samples and their further use in biobank research is subject to the prior informed consent of the donor. Biobank research is defined in the law as "research utilising the samples contained in a biobank or information associated with them for the purposes of promoting health, understanding the mechanisms of disease or developing the products and treatment practices used in health care and medical care."

The notion of consent is broad, encompassing all biobank research carried out within the purpose of the biobank. (Sect. 11, Biobank Act) The purposes of existing biobanks have, for most of them, been defined as encompassing the entire scope of activities of the university hospital hosting the biobank or the purpose of operations of the National Institution of Health and Welfare. The consent also usually includes the permission for adding complementary information of, e.g., a donor's disease history to the biobank in order for the biobank to be able to combine this sort of sensitive information with the donor's personal data. (Sect. 11 and 14, Biobank Act)^{13, 14}

The biobank may hand over necessary personal data to be combined to the data in registers at the Institute of Health and Welfare if combining data can be justified in relation to the aims of the research project and the handing over of data satisfies the terms of the law in other respects.

According to the biobank law, samples or data may be given out of a biobank presupposing that the person or entity asking for the data attaches a research plan, a statement from the competent ethics committee referred to in the Medical Research Act or other statement necessary to assess whether the requisite conditions for granting access to the samples and information are satisfied. The application must also

¹³ Opinion of the Constitutional Law Committee 10/2012.

¹⁴ See e.g. Auria Biobank information sheet and consent form <https://www.auriabiopankki.fi/people/biobank-consent-and-refusal/?lang=en>

include an account of how the processing of the samples and data is to be carried out. (Sect. 27, Biobank Act) In practice, the director(s) of the biobank evaluate the application and no separate ethical review is carried out unless there are specific circumstances calling for such review.

The provisions relating to the secrecy of health information provided for in Sect. 28 of the Finnish FoIA are nevertheless applicable also when handing out samples or data from biobanks. This means that the final decision as to whether the requisites given in the biobank law, data protection law and the freedom of information law are satisfied lies in the last instance with the organisation responsible for the biobank regardless of whether it is a public or private entity. This also means that the [person or entity receiving the data from a biobank is bound by the secrecy provisions given in the Finnish FoIA, because data included in a biobank is always health-related personal data and thus secret in terms of the FoIA.](#)

A biobank may grant access to, study or otherwise process the samples and information stored by it provided that:

1. the intended use corresponds to the research area defined for the biobank and the criteria and conditions established for the processing of the sample;
2. terms and restrictions provided for in the biobank law or other law and determined by the biobank are observed in the research and in the processing of samples and information;
3. the individual to whom access to the samples or information is granted must hold the appropriate professional and academic qualifications for processing the samples and information, and the granting of access to the sample or information is in connection with the duties of the recipient.

The samples and information associated with them shall be coded prior to granting access to them for research purposes, unless there is specific reason for not doing so. The codes used in connection with the granting of access are formed on a project-by-project basis. The codes used in the storing of samples and information may not be given out by the biobank.

The biobank law is currently under revision. The legislation relating to primary-care-related processing of personal health data is currently under revision and a proposal for a new law is expected at the beginning of 2017. Another legislative proposal covering all secondary uses of personal data from health and social security services and registers was sent for remiss in August 2016. It is proposed that all health and social security data would be available from one place for different kinds of scientific research, quality assurance, planning and administrative as well as innovation purposes. No statutory ethical evaluation is foreseen in this proposal.

ICELAND

1. Primary processing of health data for scientific research

In Iceland primary medical research is regulated foremost by the Act on Scientific Research in the Health Sector (hereafter the Health Research Act) (No. 44/2014). Clinical trials are in addition subject to the Medicinal Products Act and to the regulations issued on the basis of that act. Clinical trials related to medical equipment are subject to the Act on Medical Devices and to the regulations issued based on that act. The data protection act is applied in a complementary manner. (Art. 2, Health Research Act)

[Scientific research in the health sector](#) is defined as research on human subjects, biological samples and health data, in which scientific methods are applied in order to enhance knowledge about health and diseases. *Scientific research projects on human subjects* are defined as studies in which the individual takes an active part in research, such as by undergoing tests or providing samples or information for the study. Health data are defined as information in health records, information and data from biobanks and health databanks, and other information on medical history and health. (Art. 3, Health Research Act)

The National Bioethics Committee evaluates scientific research projects in the health sector in Iceland. It evaluates all collaborative projects, multinational projects, clinical trials of medicinal products and other scientific research protocols in the health sector unless there is an institutional review board established by a Ministerial regulation.

According to the Health Research Act, [a scientific research project may not start without having been evaluated by either the National Bioethics Committee or an institutional review board \(IRB\)](#). After the ethical approval no alterations to the nature or scope of the study are permitted without prior approval from the applicable ethical committee. Minor changes may require only a notification to the National Bioethics Committee or an IRB if determined within the rules of the National Bioethics Committee. (Art. 12)

The National Bioethics Committee or an IRB submits a [notification to the Data Protection Authority](#) with regard to each application of a scientific study. This notification consists of a summary of the study, including a description of the processing of personal data carried out in the study. The Data Protection Authority will decide within 10 days whether carrying out the study requires, for example, improved security measures for the processing of personal health data. The Data Protection Authority may also prohibit the study proposed. (Art. 13)

After the completion of a study, the health information materials, which were acquired for a retrospective study or which arise from such research, may be retained permanently in a biobank or health databank if this was provided for beforehand in the research protocol which has been approved by the National Bioethics Committee or an institutional review board.

Scientific research on human subjects always requires freely given informed consent from the participants in the research. After having received the opinion of the Data Protection Authority the National Bioethics Committee issues rules on how potential participants in scientific research are to be selected and approached, and on the information to be provided before consent is elicited. The processing of personal data in the research project is subject to the provisions of the Data Protection Act. (Art. 18, Health Research Act)

If the research project is a scientific study on human subjects [the possibility to retain and store health information materials acquired from the study is subject to the terms of the consent granted for the study](#). The permanent storage of such health data will be in a health databank or, for biological samples, in a biobank.

2. Secondary processing of health data

According to the Health Research Act, the acquisition, use and delivery of health information materials for use in scientific studies shall be in accordance with the objective of the study and with the approval granted by the National Bioethics Committee or an IRB. (Art. 16)

2.1 Biobanks

According to the Biobanks Act (110/2000, last amended 48/2009), [free and informed consent from the data subject is required for the storing of biobank samples for designated scientific research in the health sector. The National Bioethics Committee or an IRB provides the terms for the use of broad consent.](#) They may also decide that in an individual case, renewed consent is required. The research participants who have given broad consent have access to all information relating to the research. The participants may also refuse the use of their materials in specified studies, in which case their use is prohibited. The law also requires prior approval from the Data Protection Authority. (Art. 9, Biobanks Act)

Biological samples retained under the law shall be permanently stored in a biobank for use under the provisions of the Biobanks Act. Health data retained shall be permanently stored in a health databank for use under the provisions of the Biobanks Act. Participants must be informed of this. (Art. 19)

The principal investigator of a study, who deposits biological samples in a biobank or other health data in a health databank, makes an agreement with the management of the bank on arrangements for access to materials for scientific research. It shall be ensured that the use is covered by the consent given by the participants. The use must also be in conformity with the Data Protection Act. (Art. 19)

Participants in a scientific study may withdraw their consent at any time. The same applies to consent for the retention of biological samples or health data for use in subsequent research. Should consent be withdrawn, research on the relevant participant's biological samples or health data must cease.

Participants may require that their biological samples and health data are destroyed. It is not possible, however, to require this if biological samples or health data are anonymised or if the biological sample has been subsumed into other material. Destruction is also not possible in case data already comprise part of the findings of a study.

2.2 Secondary use of health information

[The National Bioethics Committee or an IRB authorises access to health information materials for scientific studies, which they have approved.](#) They may also state conditions for this use. Access is subject to the consent of the body responsible for the materials. It shall be ensured that access to biological samples and health data are provided for on an equitable basis. When access is provided to health information materials, account shall be taken of the fact that they contain confidential information. Access to biological samples shall be in conformity with the provisions of the Biobanks Act with respect to the right of biological sample donors to withdraw their consent.

With regard to [medical records](#) it is provided for in the Health Research Act that every occasion in which a medical record is examined for a scientific study, this must be noted in the record. Access to medical records shall otherwise conform with the provisions of the Health Records Act. (55/2009) According to Health Records Act, [patients may prohibit the sharing of their information in connection with other health information systems \(Art. 19\) or restrict access to their health information in joint health information systems. \(Art. 21\)](#)

NORWAY

1. Primary processing of health data for scientific research

1.1. General principles with regard to primary processing of health data

In Norway the primary processing of health data is governed by the *Act on medical and health research*. (20 June 2008/44) It covers *clinical research involving humans as well as research on biological material and personal health data*. The Norwegian Personal Data Act (PDA) (14 April 2000/31) provides for the basic principles for all processing of personal data. The act only applies to the processing of personal health data in Norway and not if the person or body responsible for the research is established in a state outside of the European Economic Area and the institution does not use tools in Norway for purposes other than purely for transfer of personal health data.

Personal health data are defined as *all data, which are regarded as confidential in the Health Personnel Act*. The Health Personnel Act defines confidential health data as information relating to people's health or medical condition or other personal information that health personnel get to know in their professional capacity. (Sect. 21, Health Personnel Act) Furthermore, all other information and assessments in respect to health issues or that are significant for health issues that can be linked to an individual person are regarded as personal health data in terms of the Health Research Act (hereafter HResA). (Sect. 4.d)

Commercial exploitation of research participants, human biological material and personal health data in general is prohibited by law. (Sect. 8) This means that, for example, providing biological materials or health data for research purposes as a for-profit activity is prohibited by law.

1.2 Ethical review of research projects

In Norway the National Committee for Medical and Health Research Ethics acts as the advisory and appeal body for the decisions of the regional ethical committees. At the regional level, there are seven regional committees for medical and health research in four health care districts. The composition and tasks of the committees are regulated in the Act of 30 June 2006/56 on ethics and integrity in research (hereafter the Research Ethics Act).

A health research project must be approved in advance by the regional committee for medical and health research ethics. (Sect. 4, Research Ethics Act) *Substantial changes* to the objective, methods schedule or organisation of the research project must also be approved by the same regional ethics committee which has granted the original approval. (Sect. 11)

The Ministry of Health and Care Services may issue regulations providing for further requirements in relation to the processing of applications and time limits for the processing and more detailed conditions for prior approval of the research project. (Sects. 10.4 and 11.3, HResA)

The project manager must submit a final report on the project to the regional committee for medical and health research ethics when the project is finished. Both negative and positive findings must be presented in an objective and methodological way. (Sect. 12.1, HResA) The regional committee may issue further stipulations as to the content of the final report. The project manager may also be asked to submit annual or extraordinary reports to the Committee. (Sect 12.2 and 3, HResA)

1.3 Biological materials

The law permits the use of *broad consents* in respect to the processing of human biological material or health data for specific, broadly defined research purposes. In this case *the regional medical and health research ethics committee may specify the conditions for the use of broad consent*. The regional ethics committee may also order the project manager to obtain *new consent when necessary*. Participants who have given broad consent are entitled to receive information about the project at regular intervals. (Sect. 14, HResA)

If there are substantial changes in the research project in relation to the collected biological material or personal health data and these changes can have an impact on the original consent granted by the research subject, new consent must be obtained. In case obtaining a new consent turns out to be difficult, the regional committee for medical and health research ethics may approve new or changed use of previously collected human biological material or personal health data without new consent. This is possible only if the research in question is of significant interest to society and the participants' welfare and integrity are ensured. In this case the regional ethics committee may lay down further requirements for such use.

It is specified in the law that consent is not required for research on anonymous human biological material and for research using anonymous data. However, *consent is required for collecting material and personal health data for subsequent anonymisation.*

2. Secondary processing of personal health data

2.1 General

The secondary processing of personal health data is regulated primarily by the Health Register Act (*Lov om helseregistre og behandling av helseopplysninger*, no.43/2014), which entered into force at the beginning of 2015 (hereafter HRegA). The processing of personal health data in connection with health records is subject to the Patient Record Act (*Lov om behandling av helseopplysninger ved ytelse av helsehjelp*, no. 42/2014), (hereafter the Patient Records Act). When not otherwise provided for in these laws, the Personal Data Act is applied to the processing of personal data. (Sect. 5, HRegA)

The HRegA applies to the processing of personal health data in the public health administration and public health services as well as in statistics, health analysis, research and quality measurements. It also applies to the processing of health data for archival purposes in the Norwegian health archive. *The law does not apply to the processing of such health data, which is regulated by the Medical and Health Research Act or Patient Records Act.* (Sect. 3, HRegA)

Personal health data may only be processed based on the consent of the data subject unless otherwise provided for by the law. The HRegA provides for the legal basis for the processing of health data for the purposes provided in the law. Specific public registers in particular areas can be set up by decree.

The law requires that the data controller must ensure that:

- a. the data are sufficient and relevant in relation to the purpose of processing;
- b. data are used only for the explicitly stipulated purpose, which is based on the legitimate activity of the data controller;
- c. data are not further used for purposes that are incompatible with the original purpose without the consent of the data subject; and
- d. data are correct and updated and are not stored longer than necessary for the purpose of processing. (Sect. 6.3, HRegA)

The processed personal data may only be identifiable to the degree that is necessary for satisfying the purposes of the processing of data in a particular case. The degree to which data are identifiable must be justified and the controller may be required to justify this in writing. (Sect. 6.4, HRegA)

The HRegA requires notification to the data protection authority in case the processing relates to sensitive personal data. (Sect. 7) *Permission is required from the data protection authority unless the processing is based on consent.* The law also provides for a possibility for the data protection authority to decide that permission is required also for the processing of certain other types of personal data than sensitive data. This can be the case if such processing would clearly violate important interests relating to the protection of privacy taking into account the nature and quantity of the processed personal data and the purpose of the processing. *No permission is required when the processing of sensitive personal data by central or municipal authorities is based on law.* (Sect. 33, PDA)

Furthermore, [secondary processing of personal health data for research purposes under the Norwegian personal data act does not require ethical approval](#), but is permitted by data protection law under the condition that there is a legitimate basis for processing. Such bases are:

1. if the data subject has given her consent; or
2. if the processor has a statutory right to process personal health data without consent for research purposes and the public interest in such processing clearly exceeds the disadvantages it might entail for the natural person. (Sects. 8 and 9, PDA)

Official population-based registers

Special population-based registers may also be set up by a Government issued decree. The terms of processing personal data, including name, year of birth, social security number and other direct identifiers in these registers are given in the decree. [The processing is permitted without consent to the extent required by the purpose of the register.](#)

Patient Records

Rights of patients with regard to the use of their personal data in patient records and health care in general is regulated in the Patient Records Act (43/2014, hereafter the PRA). The [PRA constitutes the legal basis for the processing of health data for patient care, administration and internal control and quality control purposes](#). Other purposes may be provided for by decree. For the processing of health data in accordance with the PRA no approval from the data protection authority is required.

Norway has a central [national health data register](#) set by a decree. (*Forskrift om nasjonal kjernejournal*, 563/2013) It contains core health information from citizens for the purposes of improving patient security and facilitating access to secure and structured patient data. The directorate for e-health acts as the data controller for the national health data register. [Citizens have a right to object to their data being processed in the national health data register](#). Medical personnel may if needed in their work request patient permission to gain access to the indispensable and relevant care-related data contained in the national health register. [Explicit, informed and voluntary consent from the patient is required to grant access to such data.](#) (Sect. 13, PRA)

[The data controller may also grant access to personal data in patient records for other than health care purposes. This must be based on the patient's explicit, informed and voluntary consent or be provided for by law.](#) (Sect. 20, PRA)

There is a proposal for an amendment to the HRegA which would facilitate setting up a new comprehensive law-based health data register encompassing life-time health data of all citizens in the municipalities. The data subjects could not object to having their personal data introduced in the register but [they would have the right to object to the introduction of certain types of data in the register](#). The proposal does not, however, specify the data to which the right to object would apply.¹⁵

The level of data security in the new register would be high. Social security numbers would be separately encrypted and kept apart from other, de-identified personal health data. The direct identifiers would only be accessible to a restricted group of persons within a data security department.¹⁶

2.2 Secondary processing of biological materials and related data

According to the Norwegian Biobank Act, a research biobank can be established only after having been evaluated by the regional ethical committee on medical research. Thereafter, notification to the Ministry of Health and Welfare will have to be made. (Sect. 4, Biobank Act)

With respect to secondary use [of human biological material](#) the HResA provides for a possibility for a

¹⁵ Høringsnotat, Nytt kommunalt pasient- og brukerregiste og enkelte endringer in helsepersonelloven, 2015 available at <https://www.regjeringen.no/contentassets/e1eb9f89a102406e891e78a7ac3917ed/kpr---hoeringsnotat-paa-hoering.pdf> (accessed 5 Feb. 2016)

¹⁶ Ibid. at 43.

regional committee for medical and health research ethics to rule that human biological material which has been collected by the health services in connection with diagnosis and treatment can be used for research purposes without the patient's consent. This is possible only in cases when the research in question is of significant interest to society and the welfare and integrity of data subjects has been ensured. The ethics committee may lay down further conditions for such use. (Sect. 28) (See more in detail above, Norway 1.3)

The patient must be informed in advance that in some cases human biological material may be used for research and that the patient has an opportunity to prohibit such use. An electronic register is kept containing the names of the persons that have objected to the use of their biological material for research. (Sect. 28.2 and 18.3, Health Research Act)

Hence, the so-called opt-out solution from the patient's perspective is adopted in Norwegian law with regard to using biological samples for research. It should, however, be emphasised that the law also requires that the research is of significant interest to society and the integrity of the data subjects is ensured. This must be evaluated by the ethics committee which also lays down the specific conditions for undertaking the research in question.

The transfer of human biological material to and from *foreign countries requires an approval from the regional committee for medical and health research ethics.* The approval presupposes that the requisites of the law relating to consent and general provisions relating to research using personal health data (Ch. 7, HResA) are satisfied.

According to the decree relating to the transfer of biological material or data derived from it abroad, the transfer requires permission from the Ministry of Health and Welfare. No permission is required if data transferred are anonymised or de-identified¹⁷ and the material or data are based in Norway or are sent abroad for analysis or quality control and the results are delivered back to Norway. In addition, if the samples are destroyed immediately after use or returned to Norway, no notification to the Ministry is required.¹⁸

If an international research project has Norwegian anonymised or de-identified participants, biobank data can be exchanged within the project without notification to the Ministry. (§4) The decree also provides for a possibility for obtaining general approval for continuous transfer of biological material or data to a foreign country under certain conditions. (Ch. 3 of the decree)

¹⁷ De-identified data are defined in the decree as personal data from which all direct identifiers have been removed.

¹⁸ Sect. 3, Forskift om overføring av biobankmateriale til utlandet, 2004:511

SWEDEN

1. Primary processing of health data for scientific research

1.1. General principles relating to ethical review of health research projects

In Sweden there are six regional ethical committees and one Central Ethical Review Board, which is also the appellate body for the decisions of regional ethical committees. The decisions of the Central Ethical Review Board may not be appealed. (Sections 24–30 for regional ethical boards and 31–37 for the Central Ethical Review Board, Ethical Review Act (460/2003))

Ethical review of research projects constitutes a central element for granting research permissions and access to secondary sources of health-related data in Sweden. According to [the Ethical Review Act](#), it is applied to all research where sensitive data as defined in the [Personal Data Act \(204/1998\)](#) are being processed for research purposes. This applies for both primary and secondary use of health-related data and regardless of the fact whether the research is based on consent or not. In the law research is defined as scientifically experimental or theoretical work intended to result in new knowledge and development outcomes on a scientific basis, excluding work that is performed within the framework of higher education on the basic or advanced level. (Sect. 2, Ethical Review Act)

With regard to primary processing of health data the law applies to research that:

1. subjects a research subject to a physical intervention;
2. is performed according to a method with the purpose of affecting a research person physically or mentally, and which includes an apparent risk of injuring the research subject, either physically or mentally;
3. relates to studies of biological material that has been taken from a living person, and can be traced to that person;
4. constitutes a physical intervention on a deceased person; or
5. relates to studies of biological material that has been taken from a deceased person for medical purposes and can be traced to that person. (law 192/2008)

In this respect, the scope of ethical review is similar to that in other Nordic countries in which both interventional research and research using biological materials stored in a biobank are subject to statutory ethical review.

1.2. Informed consent

Primary processing of health-related data requires informed consent from the research subject. According to the Ethical Review Act, the consent has to fulfil the information requirement set out in the law, according to which the data subject must be informed of the following issues:

1. the overall plan of the research;
2. the purpose of the research;
3. the methods that will be used;
4. the consequences and risks that the research might entail;
5. the identity of the responsible research body;
6. the fact that participation in the research is voluntary; and of
7. the right of the research subject to cease participating at any time. (Sect. 16, Ethical Review Act)

Furthermore, consent must be voluntary, explicit and specific to particular research. Consent must also be documented. (Sect.17, Ethical Review Act) If any of these requirements are not fulfilled the consent is

regarded as invalid. Consent may be revoked at any time and with immediate effect. Data that have been collected prior to this may be used in the research. (Sect. 19)

The law provides for special rules for circumstances when research can be conducted without consent on the basis that the research subject is incapable of expressing an opinion.

2. Secondary processing of health data

2.1 Register-based data

Using register-based data for scientific research is governed by the Swedish Freedom of Information Law, that is the Public Access to Information and Secrecy Act (2009:400), and the Freedom of the Press Act. (*Tryckfrihetsordningen*, 1949:105) According to the Freedom of the Press Act, protection of personal or economic circumstances of private individuals is grounds for keeping official, otherwise public, documents secret. (Ch. 2, Sect. 2.1(6)) The Public Access to Information and Secrecy Act provides for more detailed regulation as to the secrecy of specific information with regard to personal and economic data. Chapters 21–40 of the law are of relevance in this respect.

Handing over data for research purposes is thus subject to, on the one hand, the Freedom of the Press Act, and the Public Access to Information and Secrecy Act and the ethical review Act and Personal Data Act on the other hand. According to the Swedish Personal Data Act, [sensitive personal data may be processed for research and statistical purposes provided that the processing is approved by ethical review conducted according to the Swedish Ethical Review Act.](#) (2003:460) In addition, [the processing must satisfy the general requisites for data processing given in the personal data act](#), that is the recipient of the personal data must have the right to process the data. . At last instance, it is [the register-hosting authority, which has the obligation to determine whether there is a basis for handing over data for research purposes in each individual case.](#)

2.2 Patient records

The personal health related information contained in patient journals and electronic health records in the public sector is also subject to strong secrecy provisions according to the Public Access to Information and Secrecy Act. (Chapt. 21 and 25) The secrecy may be broken by the person herself which means that the journal may be used for research purposes when there is a consent from the data subject. (Chapt. 12)

The journal may also be used for research purposes when the research project is approved by the relevant ethical committee and if the person responsible for the care of the patient in the institution determines that handing over information contained in the journal does not cause harm to the data subject.

The law also provides for transferring of the statutory secrecy obligation in certain cases where patient information is handed to another public authority. This also applies to situations when the receiving public organization processes the data for research purposes.¹⁹

2.3 The processing of data from quality registers for health research

At the national and regional level in Sweden there are quality registers in which information relating to primary health care for quality control and decision-making purposes is systematically being collected. Information from primary health care is also reported to several national quality registers. Quality registers are defined in the law as *automatic and structured collections of personal data which have been set up for the purposes of systematic and continuous development and security control of the quality of health care*. The law applies to such national and regional quality registers for which personal data are collected from several providers of health care. (Ch. 7:1, Patient Data Law)

The legal basis for processing personal data in quality registers lies in the [Patient Data Law](#). (2008:355) The law provides for [the legal purposes of processing data in such registers](#). Patient data from quality registers

¹⁹ Chapter 25 provides for the secrecy provisions and exemptions thereof for handling patient data in health care.

may be processed only for statistical purposes and for [research within health- and patient care](#), when handing over information for such purposes as well as for other purposes required by law without prejudice to Ch. 6, Sect. 5 of the Public Access to Information and Secrecy Act, which regulates information exchange between public authorities.

[Patient data may be included in a quality register unless the patient prohibits it](#). This means that the opt-out solution is adopted in the law in this respect. If the patient opposes the processing of personal data after the care has already begun, data must be taken out of the register as soon as possible. (Ch. 7:2, Patient Data Law) Legislation also provides for procedures for dealing with processing in situations when the patient does not have the capacity to decide whether her personal data may be processed.

Before personal data are processed in a national or regional quality register the data controller must inform the patient about her rights to prohibit the processing at any time. The patient must also be given information as to what extent personal data are collected from other sources than from the person herself or her patient record and as to what categories of recipients the data may be handed over to. Only central or regional public authorities in the health care sector can be data controllers of quality registers.

Only personal data which is necessary for each processing purpose as provided by the law may be processed in a quality register. Personal social security numbers or names may only be processed in a quality register if the purpose of the register cannot be achieved with coded personal data or data that can only indirectly be connected to an individual.

Other sensitive information than health information cannot be processed in a quality register unless the government or government-appointed authority has permitted this.

2.4 Regulating biobanks in Sweden

Biobanks are regulated in Sweden by the Biobanks in Medical Care Act. (297/2002) The law covers biobanks within the health care system and applies only to the storing of tissue samples and the processing of data necessary to track the donor. [Other forms of processing of personal data from the biobank are covered by the Personal Data Act. Establishing a biobank for research purposes or for clinical trials requires prior authorisation from the relevant research ethics committee.](#) After that the biobank may only be used for that purpose without further approval from the research ethics committee. (Ch. 2, Sect.3)

Under the law the use of samples from the biobank for research purposes requires permission from the data subject. Consent is required also in cases in which the samples are coded when delivered to the researcher. Tissue samples from a research biobank may also be sent to another unit for research both in Sweden and abroad with the consent of the donor. (Ch. 4, Sect. 5)

When already-existing samples are used for research purposes or for clinical trials, the research ethics committee that approves the new purpose for this biobank determines also the requirements relating to the information and consent regulations that must be applied so that the tissue samples may be used for such a new purpose. (Ch. 3, Sect. 5) The released tissue samples must be depersonalised or coded, unless otherwise decided. Code keys are kept on the premises of the care provider and stored securely. (Ch. 3, Sect. 4) If a donor's personal details are released at the same time as a coded tissue sample from the same donor they must be released in such a way that the personal details can not be connected with the tissue sample. (Ch. 3, Sect. 10)

2.5 Cross-border processing of health data

Health-related data are always regarded as sensitive data in terms of the Swedish data protection law. This means that [all research involving the processing of health-related personal data is subject to ethical review in Sweden](#). If the research requires data from public registers, the data may be released after ethical review of the research project, unless otherwise prohibited by the rules on secrecy and confidentiality and the assessment of the register-hosting authority in the individual case. Thus, the ethical review process constitutes a central part of the data protection of research subjects and is required in Sweden by law, also in cases where in Denmark, Finland, and Norway notification to or authorisation from the data protection authority is sufficient. In Iceland ethical review is required in all health research projects.

It is somewhat unclear whether it is possible to obtain data from public registers for research purposes from Sweden if the research as such takes place outside of Sweden. The prevailing opinion seems to interpret the law on ethical review as being strictly applicable only to such research that takes place in Sweden as stated in Sect. 5 of the ethical review law. According to the decree on ethical review (2003:516), it is possible to obtain ethical review also in cases where the principal investigator is outside of Sweden or the place of research is not determined. In this case the competent ethical review committee is the one in whose area the research mainly takes place. (§3) If the research takes place outside of Sweden, this does not give us any further guidance as to the state of law.

This seems to lead to a situation in which there always has to be a research partner in Sweden in order to get personal data from Swedish public sources for research undertaken in another EU country. There is no problem in this respect if the research data are acquired based on consent which explicitly permits the transfer of data within the EU and/or to a third country.

In Denmark the practice of register-hosting bodies has also led to a similar requirement which, however, is not based on the requisites of ethical review but rather on the internal guidelines of register-hosting bodies. The same seems to be true for all Nordic statistics organisations unless the data are anonymous or de-identified.

3. THE IMPACT OF GENERAL DATA PROTECTION REGULATION ON THE COORDINATION OF ETHICAL REVIEW PRACTICES IN THE NORDIC COUNTRIES



OSLO, NORWAY
Photo: Tyler Olson/Shutterstock

3. THE IMPACT OF GENERAL DATA PROTECTION REGULATION ON THE COORDINATION OF ETHICAL REVIEW PRACTICES IN THE NORDIC COUNTRIES

3.1 General provisions relating to the processing of health-related data

The General Data Protection Regulation (hereafter the GDPR) was finally agreed upon in December 2015 and published in the EU Official Journal on 4 May 2016. It will be applied as law in all Member States and within the EEA as of 25 May 2018.²⁰

The general provisions relating to the use of personal information for research purposes do not, generally speaking, differ much from those that were provided for in the data protection directive 95/46/EC. The Regulation provides for more specific exceptions from the general rules for the benefit of processing personal data for scientific research purposes. *The processing of health-related data is subject to stricter requirements* than the processing of most other types of personal data. In the following we shall give an overview of the provisions of the Regulation as related to the processing of health-related data for scientific research purposes after which we shall discuss what impact, if any, these provisions could have on the possibilities of coordinating ethical review in relation to health research projects within the Nordic countries.

Health-related data are given an extensive definition in the Regulation. According to the Regulation, health-related data are defined as *personal data related to the physical or mental health of an individual, including the provision of health care services, which reveal information about his or her health status*. In the recitals of the Regulation, data concerning health is further defined as including *all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services as referred to in Directive 2011/24/EU of the European Parliament and of the Council (9) to that natural person; a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test.* (Recital 35)

In principle, the processing of health data is prohibited but can be permitted under the specific conditions provided for in the Regulation. According to the *Regulation, special categories of personal data which deserve higher protection may only be processed for health-related purposes where necessary to achieve those purposes for the benefit of individuals and society as a whole ... for scientific and historical research purposes or statistical purposes based on Union or Member State law which has to meet an objective of public interest, as well as for studies conducted in the public interest in the area of public health.* (Recital 42a)

²⁰ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 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 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2016:119:TOC>

It is further stated that *Union or Member State law should provide for specific and suitable measures so as to protect the fundamental rights and the personal data of individuals. Member States should be allowed to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or health data. However, this should not hamper the free flow of data within the Union when those conditions apply to cross-border processing of such data.* (Recital 53)

This gives the Member States the possibility to introduce even stricter provisions for the processing of sensitive data for health-related purposes. For the processing of sensitive data for health-related scientific research this would entail that it should be based on Union or Member State law which has to meet an objective of public interest. If the processing is even further restricted in national law, it should in any case permit the cross-border processing of such data. In other words, this appears to preclude, for example, any local processing requirements for the processing of e.g. register-based data in a national register-hosting or research organisation unless access to the system is provided for also for other EU –based researchers. This also calls into question the Swedish practice of conducting ethical review for only research conducted in Sweden and thus preventing *de facto* the free movement of personal data for research purposes within the EU.

For scientific research, health data may be processed on the basis of explicit consent for one or more specified purposes (Art. 9.1(a)) or on other legal bases given in the Member State or Union law. According to the Regulation, the processing of health data may also be possible without consent in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject. (Art. 9.2(j))

According to the GDPR, 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.* In addition, any national regulation should take into account the Union's objective under Article 179(1) of the Treaty on the Functioning of the European Union of achieving a European Research Area. Scientific research purposes should also include studies conducted in the public interest in the area of public health. (Recital 159)

In the following we shall first analyse the provisions relating to consenting to the processing of personal data for scientific research and thereafter the specific provisions in the Regulation under which Member States may enact national law with regard to the processing of personal data for scientific research.

3.2 Consent

The provisions of the Regulation relating to consenting to the use of personal data for research purposes are more explicit than in the current data protection directive (95/46/EC), in particular with regard to the processing of health-related data.

The general rule for consent is that it must be given for one or more specific purposes. (Art. 6.1) With respect to sensitive data, such as health-related data, consent must be *explicit for one or more specified purposes.* When processing is based on consent, *the controller must be able to demonstrate that consent was given by the data subject to the processing of their personal data.* (Art. 7.1) In European data protection law, specific consent is regarded as requiring that the data subject has some knowledge of the purpose of the processing. Vague notions such as 'future research' are not regarded as sufficient if they are not further qualified.²¹

²¹ Working Party 29, Opinion 3/2013 on purpose limitation, at 52.

If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent must be presented in a manner which is clearly distinguishable from such other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of the declaration which constitutes an infringement of the Regulation is not binding according to the Regulation. (Art. 7.2)

This is very important also with regard to giving permission to match personal health data with data from other sources such as with the data arising out of clinical trials. [If clinical trial data are matched with other personal data, such as register-based data, separate and explicit consent is required from the data subject](#) as required by the current EU data protection directive and the new EU data protection regulation for health data. According to the Clinical Trials Regulation, scientific research making use of the data outside the protocol of the clinical trial shall be conducted in accordance with the applicable law on data protection. (Clinical Trials Regulation, Art. 28.2(2))

According to the Clinical Trials Regulation it is necessary that the data subject gives a separate consent to use his or her data outside the protocol of the clinical trial and has the right to withdraw that consent at any time. It is also necessary that research projects based on such data are made subject to reviews that are appropriate for research on human data, for example on ethical aspects, before being conducted. (Clinical Trials Regulation, Recital 29)

[The data subject has the right to withdraw his or her consent at any time.](#)

The withdrawal of consent does not affect the lawfulness of processing based on consent before it was withdrawn. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw consent as to give it. (Art. 7.3, GDPR)

When assessing whether consent is freely given, it will be of the utmost importance to establish whether, i.a., the performance of a contract, including the provision of a service, is made conditional on the consent to the processing of data that is not necessary for the performance of this contract. (Art. 7.4) This is important to remember, since a doctor-patient setting often constitutes an unbalanced power setting, which is why it is recommendable that consenting with regard to the processing of personal data for research purposes is done separately and by personnel other than care providers.

It is recognised in the Regulation that the purposes of scientific research cannot always be fully identifiable at the time of the collection of the data. To accommodate this fact the Regulation allows [that consent can be granted for certain areas of scientific research when in keeping with recognised ethical standards for scientific research](#). However, data subjects should [always 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](#). (Recital 33) Moreover, consent is presumed [not to be freely given if it does not allow separate consent to be given to different data-processing operations](#) despite this being appropriate in the individual case. (Recital 43)

This provision clearly opens up the possibility of adjusting the otherwise stringent rules relating to consent to specific types of scientific needs. In drawing the lines for appropriate consents in health-related scientific research a dialogue between researchers and data protection lawyers is called for. However, it is clear that the framework set out by the Regulation for the processing of health-related data for scientific research must be respected and any deviation from the level of protection afforded to the data subject at the national level may only be to the benefit of the data subject. Hence, the consents for processing health-related data should be for one or more specific purposes which are explicitly distinguished in writing from one another. The data subject should also have the possibility to delimit the scope of consent to a certain type of research or part of research project as appropriate to the research in question.

The transitory provisions of the Regulation state that where processing is based on consent pursuant to Directive 95/46/EC, it is not necessary for the data subject to give his or her consent again if the manner in which the consent has been given is in line with the conditions of this Regulation, so as to allow the controller to continue such processing after the date of application of this Regulation. (Recital 171) This seems to suggest that all consents should be in line with the Regulation if the processing still continues after the Regulation is applicable, that is as of 25 May 2018. In consequence, insofar as the primary processing of data is based on consent, these consents should be checked and updated to conform with the Regulation by

May 2018 if the data are still being used at that time. It is recommendable that new consents are drafted in conformity with the Regulation already before that time.

3.3 Specific provisions relating to the processing of personal data for scientific research

The legal basis for processing sensitive personal data for scientific research without the consent of the data subject can be given by law subject to the conditions given in the Article 89.1 of the GDPR. Article 89 requires that appropriate safeguards are provided for in the law for protecting the rights and freedoms of the data subject. These safeguards must, according to the GDPR, ensure that technical and organisational measures are in place, in particular in order to ensure the respect of the principle of data minimisation. This means that no more personal data than are strictly required to satisfy the needs of the research in question can be collected. As one of the safeguards, the Regulation mentions [pseudonymisation](#) of the data. However, it is stated that whenever the purposes of research can be fulfilled by the further processing of data, which does not permit or no longer permits the identification of data, this is preferable.

The Regulation also gives Member States a large room for manoeuvre to derogate from some of the basic rules of the Regulation. Member States are given the possibility to provide in their national law, in the presence of appropriate safeguards for data subjects, specifications and derogations from the following provisions of the Regulation under specific conditions:

- information requirements to the data subject;
- rectification;
- erasure;
- right to be forgotten;
- restriction of processing;
- right to object to processing.

The possible implementation of these derogations in national law must be strictly tied into the achievement of the purposes of the research in question, which means that [they may be applied only in so far the enforcement of these rights could render impossible or seriously impair the achievement of the specific purposes of research](#). (Art. 83.2) Consequently, any derogations from these rules must be [necessary for the fulfilment of the specific purposes of research and subject to the conditions and safeguards provided for in Article 89\(1\)](#).

The conditions and safeguards in question may entail specific procedures for data subjects to exercise those rights if this is appropriate in the light of the purposes sought by the specific processing, along with technical and organisational measures aimed at minimising the processing of personal data in pursuance of the proportionality and necessity principles.

Further processing of personal data for scientific research purposes presupposes that the data controller has assessed the feasibility of fulfilling those purposes by processing data which does not permit or no longer permits the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data and a secure technological environment). Member States are thus obliged to provide at the national level appropriate safeguards for the processing of personal data for scientific and historical research purposes or for statistical purposes.

3.4 Public Access to Official Documents and the GDPR

In the Regulation it is explicitly stated that it allows the principle of public access to official documents to be taken into account when applying the provisions set out in the Regulation. Personal data in documents held by a public authority or a public body may be publicly disclosed by the authority or body if the disclosure is provided for by Union law or Member State law to which the public authority or public body is subject. Such laws should reconcile public access to official documents and the re-use of public sector information with the right to the protection of personal data and may therefore provide for the necessary reconciliation with the right to the protection of personal data pursuant to this Regulation. (Recital 154)

However, according to the GDPR, the Directive 2003/98/EC on the re-use of public sector information (the PSI Directive) leaves intact and in no way affects the level of protection of individuals with regard to the

processing of personal data under the provisions of Union and national law and. In particular, it does not alter the obligations and rights set out in the GDPR. Hence, the PSI Directive does not apply to documents or parts of documents, access to which is excluded or restricted by virtue of the access regimes on the grounds of the protection of personal data.

What this means is that public sector bodies are not subject to the PSI Directive for the purpose of opening access to their data containing personal information for re-use purposes. However, [when access to national population-based registers is governed by national laws relating to access to official documents, this arrangement can be maintained for the benefit of processing personal data for scientific research subject to the requirements and safeguards given in the GDPR.](#)

[Further processing of personal data for the purposes of register-based research is explicitly mentioned as permitted under the conditions set out in the Regulation.](#) (Recital 157) Data should preferably be in anonymised or pseudonymised form and used in technologically and administratively safe settings. The general requisites for processing must also be in place, which means that there has to be a legitimate basis for the processing of personal data for research purposes. In practice, this means that register-based research can go on as before but in anonymised or pseudonymised form with organisational and technological safeguards.

[Assessment of the risks involved in a particular type of data processing is explicitly called for in the Regulation when processing, on a large scale, health-related data and genetic data.](#) A data protection impact assessment has to be carried out prior to the processing and it consists of an assessment of the impact of the envisaged processing operations on the protection of personal data. A single assessment may address a set of similar processing operations that present similar high risks. It can be carried out in cooperation with the data protection officer. (Art. 35)

* * *

The provisions relating to research in the GDPR were among the last ones to have been agreed upon in the institutional Trilogue and as such reflect to a certain extent last-minute pressure for a compromise. This is particularly apparent in the fact that these provisions are one of the few instances in which [Member States are provided with considerable national leeway for drafting their own national legislation relating to the processing of personal data for scientific research purposes within the limits set out by the Regulation.](#) Health data are subject to a more stringent set of rules, in particular relating to consent, and [Member States are given the possibility to enact legislation where the protection conferred to data subjects in health research is higher than required by the Regulation](#) as long as these rules do not raise obstacles to the achievement of the European Research Area.

In practice this means that if no specific national legislation is enacted the general rules of the Regulation will apply also for scientific research. Moreover, with regard to consent for health research this means that if the current consents are not in line with the requirements of the Regulation in this respect the consent will no longer be valid and no data can be processed based on those consents. With regard to consents and health research in general the provisions of the Regulation provide for the minimum level of protection for the data subject and the Member States have the possibility to provide for stricter conditions for the processing of health-related data in the national law.

4. CONCLUDING REMARKS AND A WAY FORWARD





REYKJAVIK, ICELAND
Photo: Kaylinka/Shutterstock

4. CONCLUDING REMARKS AND A WAY FORWARD

4.1 Legal possibilities for coordinating ethical review practices between the Nordic countries

When we compare the use of ethical review in health research in different Nordic countries there seems to be a difference insofar as ethical review in Sweden is statutory as it is a legal prerequisite for processing sensitive personal data for research uses under Swedish law. Furthermore, in Sweden the constitution of ethical review is strictly regulated requiring that the chairperson is a judge or someone with equivalent legal background. There are clear rules relating to the appeal process for decisions by a regional ethical board. In Iceland there is also a comprehensive new law which regulates health research and has integrated ethical review at all levels.

The fact that the Swedish law relating to ethical review states that it is applied only for research conducted in Sweden has led to a situation in which, in practice, it is impossible for researchers outside of Sweden to obtain sensitive personal data for research purposes, because the ethics committees will not assess the applications unless some of the research is also conducted in Sweden. This has led to a situation where, for example, *socialstyrelsen* will not give out any register-based personal data for research projects which do not have Swedish participants and Swedish ethical approval. However, the final decision in this lies, according to the law, solely with the *socialstyrelsen*.

Denmark, Norway and Finland have to a large extent a similar system with regard to statutory ethical review in health research involving humans, although in Denmark, ethical review is required by law more often than in Finland and Norway. In particular, with regard to the use of health data in health records, the new Danish law provides for a comprehensive legal framework. In Norway the use of health data in patient records is subject to patient consent and another law relating to municipal health registers is under preparation. In Finland a proposal for a comprehensive law relating to secondary uses of health and social security data was sent for remiss in August 2016. The overall regulation of health research projects differs somewhat in Norway and Finland, but both countries have statutory ethical review for health research that is regulated under health research laws and encompasses also research conducted with biological materials and research affecting the mental well-being or capacities of individuals.

In Finland, biobank-related research is subject to specific legislation according to which primary collection of biobank materials and secondary use of data derived from those materials are subject to medical research law and ethical review or equivalent evaluation provided in that law. Data protection law is applied in a supplementary way to the processing of personal data relating to the materials in the biobank. In addition, the relevant provisions of the Finnish FoIA with regard to secrecy of personal health and social security information are applied to accessing data from biobanks. This law is currently under revision.

The secondary use of health-related data, with the exception of biobank data, does not require automatic ethical review in Denmark, Norway and Finland. In Denmark and Norway prior authorisation from the data protection authority is required. In Finland notification to the data protection authority is sufficient. In addition, for example in Finland, when health-related data are released for research purposes from public registers research permission is required by the data protection law (§14, DPA) and getting this permission in medical research requires an ethical review. In most cases ethical review is carried out either by the regional ethics committee or within the register-hosting institution or, in some cases, by both.

Removing bureaucratic obstacles from cross-border research projects in the Nordic countries is an important goal. Given the somewhat differing national legislations in this respect, achieving this will entail legislative changes. This is something that could be looked at more closely at the Nordic level when the data protection laws are being revised in connection with drafting the national provisions relating to the processing of personal data for research purposes as provided for in the GDPR. [Ethical review could be regarded as one of the safeguards](#) called for in the GDPR when personal data is processed for research purposes without consent of the data subject.

4.2 Nordic harmonisation possibilities within EU General Data Protection Regulation

In addition to the slightly different legal approaches with regard to regulating, in particular, secondary processing of health data for research purposes, there may be other differences at the practical level that also have an impact on the ethical evaluation of research. This is the case with regard to the varying national requirements for the scope of consents for the primary processing of health data and in the processing of data from biological materials stored in biobanks, in particular.

This is something that the GDPR has sought to clarify and harmonise at the Community level providing strict requirements for the minimum requisites for consenting to the processing of health-related data for scientific research. Even if national legislators are left with some space for manoeuvre also in this regard, one of the common threads for consent is that [there should be a possibility to give consent only for certain areas of research or parts of research projects to the extent allowed by the intended purpose. Moreover, consent is presumed not to be freely given if it does not allow separate consent to be given to different data processing operations despite this being appropriate in the individual case.](#) For determining how the different areas of research for the purposes of delimiting consent could be defined, the GDPR refers to [the recognised ethical standards for scientific research.](#)

Recognising the existing different practical requirements for the scope of consent in the Nordic countries at the moment, this could be one area where Nordic cooperation could be strengthened and common ground could be sought. All the Nordic countries will have to revisit their requirements for consent during the next months and all existing consents will have to be updated by that time if processing is still to be based on them. This could provide for a great Nordic opportunity for harmonising one of the data protection cornerstones relating to scientific research.

In the same connection, steps should be taken to study the extent to which it would be possible for the Nordic countries to harmonise the provisions of the GDPR referring to Member States' national laws to provide for organisational and technological safeguards in connection with the processing of personal data for research purposes (Art. 89.1) and the possibility for derogating from certain general rules of the GDPR for facilitating research uses. (Art. 89.2) Common legal provisions with regard to national implementation of the safeguards applicable to the processing of personal data for scientific research could thus lay part of the legal foundation for the Nordic research area.

Since access to register-based data in most Nordic countries is also subject to freedom of information laws, that is access to official documents and secrecy laws, the interoperability and balancing of these laws with

the GDPR will have to be carefully analysed in connection with updating national laws in line with the new EU legislation. In particular, the current strict interpretation of the secrecy provisions included in the statistics acts and Swedish Public Access to Information and Secrecy Act can [confine, in certain cases, the application of the law to national territory, thus excluding in practice the delivery of, or access to, such register data from other EU countries](#). Moreover, if mandatory ethical review for any release of personal data for research purposes is only available for research conducted in the home country, this in practice leads to [a local processing requirement](#), which can be problematic under EU law.

The GDPR provides the Member States with a possibility to apply further conditions for the processing of, in particular, genetic and biometric data and health-related data but such conditions should not, however, hamper the free flow of personal data within the Union when those conditions apply to cross-border processing of such data. (Recital 53) [The conditions for cross-border research in light of the GDPR are something that should be further analysed in future work](#).

An emerging field of medical research relates to using text and data-mining algorithms to retrieve new information from e.g. patient records and medical journals. In addition to data protection issues, this research is confronted with copyright questions if access to and the possibility for data analysis is not explicitly provided for by the scientific journal or data-hosting organisation. A common legislative approach in respect to using data-analysis techniques for mining data in scientific journals, patient records and public population-based registers and matching this with other data would provide important added value to Nordic medical research. The European Commission has published its legislative proposal with regard to these issues in the context of its copyright reform.²² It would be in the interest of the Nordic scientific community to have a common Nordic position with regard to copyright exceptions for text and data mining for scientific research.

22 Proposal for a directive of the European parliament and of the council on copyright in the Digital Single Market, COM/2016/0593 final - 2016/0280 (COD).

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The legal building blocks for the future Nordic Research Area or even the Nordic Research Commons are now given at the European level. All we need is to find the appropriate Nordic application of these rules in order to be able to carry out research at an integrated Nordic level. The future Nordic Research Area could be envisaged as being based on an interoperable secure network of systems of sharing personal data for research purposes. Subject to appropriate consents and technological and organisational safeguards, this could include personal data from clinical studies, official public registers and biobanks as well as real world data from quality registers and other similar sources, including researchers' own data. When these data are added to the data from published sources, such as scientific journals, the possibility for applying different data analysis techniques would give us a new and richer understanding of the health and well-being of the Nordic populations and open up new avenues for research and product development.

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