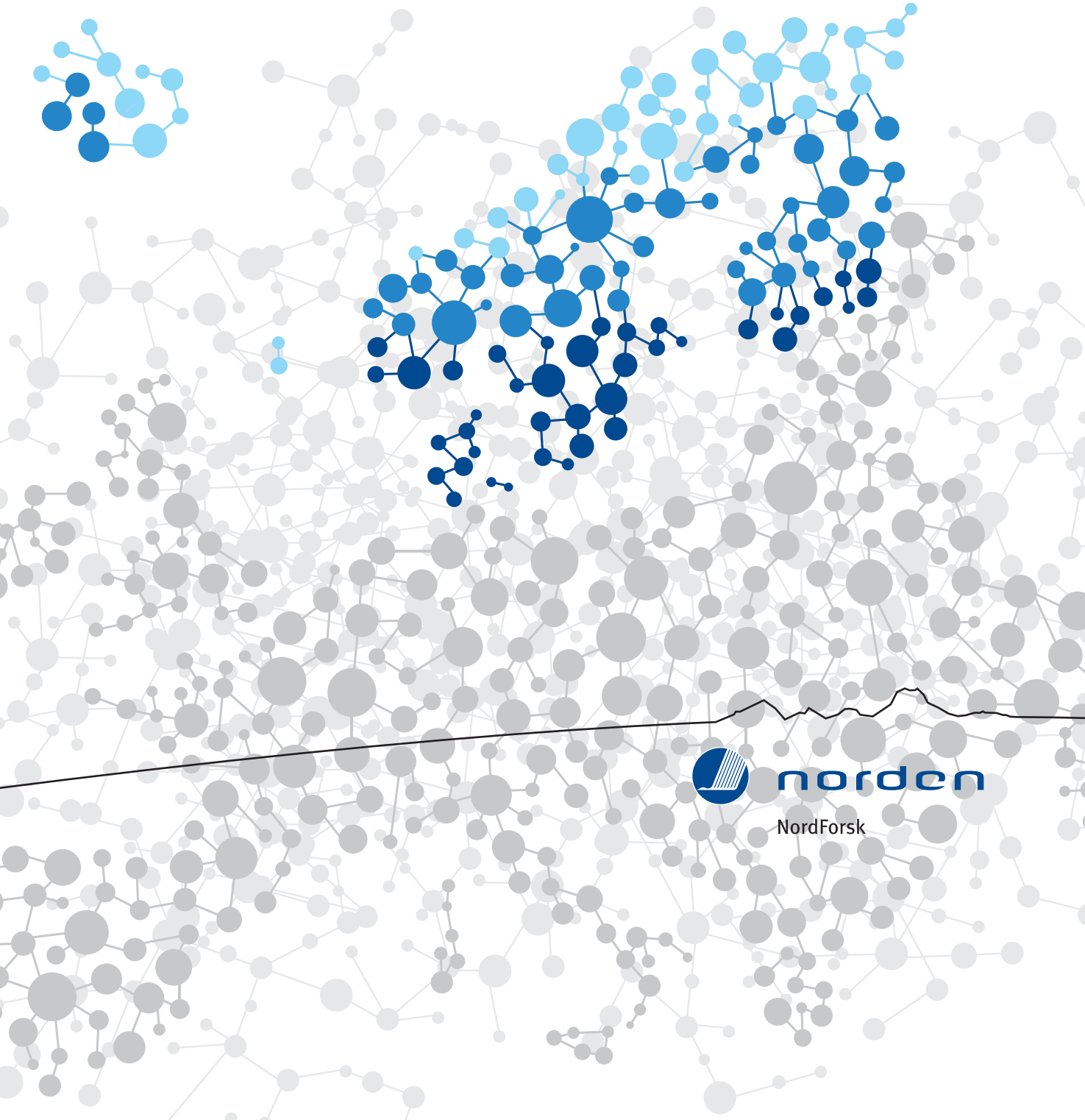
Joint Nordic Registers and Biobanks

A goldmine for health and welfare research



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Joint Nordic Registers and Biobanks
A goldmine for health and welfare research

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Joint Nordic Registers and Biobanks

A goldmine for health and welfare research

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Preface

NordForsk is an organisation under the Nordic Council of Ministers that aims to facilitate cooperation in all fields of research and research-driven innovation 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. NordForsk's preparatory actions are normally based on recommendations from Nordic Research and Innovation Area Networks (NORIA-nets), which usually include representatives of Nordic research funding agencies and experts within the respective target areas. This report is based on such a NORIA-net, whose mandate has been to provide strategic advice to the NordForsk Board on how to utilise Nordic registers and biobanks in a coordinated manner.

Register-based research within the field of health and wellbeing has great potential for producing knowledge that can be used to improve the capacity of the Nordic welfare states. This new knowledge can be translated into practical solutions, for example, for prevention, intervention and medical treatment. It can also be used to provide new means for combating social problems such as the disintegration of certain immigrant groups, youth unemployment and improving quality of life for the elderly, etc.

If properly coordinated, Nordic registers and biobanks can provide policy-makers and important actors with new, research-based knowledge. Nordic register-based research has the potential to attract international interest and achieve a world-leading position. This NORIA-net has focused its activities on how to overcome existing obstacles that impede Nordic data sharing and has proposed ways of enhancing coordination to strengthen Nordic register-based research.

NordForsk would like to offer its sincere thanks to the enthusiastic and knowledgeable NORIA-net team: Mikael Fogelholm, Erland Hjelmquist, Ilmo Keskimäki, Jan-Eric Litton, Salvör Nordal, Jørn Olsen, Juni Palmgren, Elisabeth Rynning, Marjut Salokannel, Stig Slørdahl, Eskil Wadensjö and Daniel Holmberg.

Oslo, autumn 2014

Gunnel Gustafsson
Director of NordForsk

1. A Nordic goldmine for research

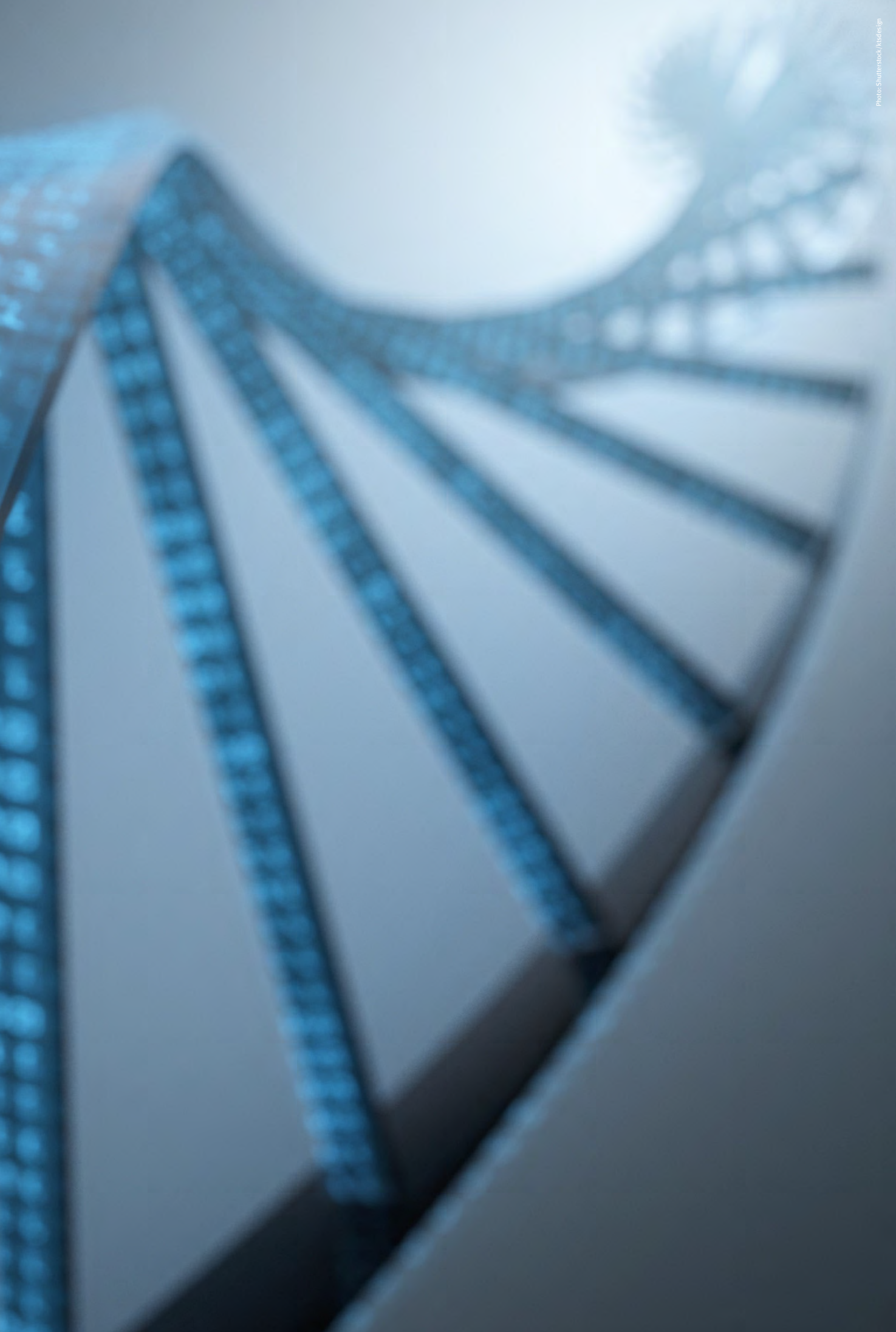

Photo: Shutterstock/ktsdesign

Introduction

This report is based on the work of the NORIA-net on Registers and Biobanks (NRB), a Nordic working group of key actors involved in Nordic research and research policy at the national level. The NORIA-net was funded from 2012 to 2014 by NordForsk, which also provided secretariat services.

The mandate of the NRB was to give strategic advice to NordForsk on how to strengthen Nordic register-based research. The group was also charged with identifying barriers impeding and potential limitations to Nordic cooperation, and proposing ways of overcoming these. Efforts could also include strategic planning and establishment of activities directed towards a common policy or other ways of strengthening Nordic cooperation.

It was clear from an early stage that the area would benefit from increased coordination at the Nordic level. The NRB therefore focused its activities on challenges and opportunities related to Nordic cooperation on databases and registers. Nordic stakeholder workshops were held to discuss how the present and future situation of the joint use of Nordic registers for research could be improved.

A Nordic expert meeting, "Responsible Data Sharing Across Borders", was organised together with the Swedish Presidency of the Nordic Council of Ministers 2013 and held at Rosenbad, Stockholm, in March 2013 (Annex 1). The purpose of the meeting was to discuss existing obstacles that impede Nordic collaboration on registers and biobanks and how these could be overcome in order to create a Nordic data-sharing framework. The expert meeting was a unique and very timely event, bringing together Nordic policy-makers, representatives of various authorities (such as bureaus of statistics, data protection agencies and ethics committees), and researchers and research funders for the first time. The NRB's proposal for a Nordic data-sharing framework was discussed at the meeting.

In November 2013, Nordic data sharing was discussed at the conference "Joint Nordic Focus on Research Infrastructures – Looking to the Future". The conference was organised under the Swedish Presidency of the Nordic Council of Ministers (NCM) 2013 by the Swedish Ministry of Education and Research, Swedish Research Council, the NCM and NordForsk. The meeting culminated in a list of actions paving the way for increased Nordic cooperation on registers, biobanks and interventional research.

This report concludes the work of the NRB and includes recommendations for the future.

"The Nordic countries should remain world leaders in using and combining register data for the benefit of people and societies while simultaneously respecting the human rights and privacy of individuals."

– Vision of the NRB working group 2012

1. A Nordic goldmine for research

The Nordic countries have a unique asset in their excellent administrative registers, longitudinal databases and biobanks, often referred to as the "Nordic goldmine". Use of these datasets in research can produce new knowledge to improve Nordic public health and welfare. However, these registers are currently not being used to their full potential in research. There are great benefits to be gained from properly coordinating the registers for use as a joint Nordic resource.

The Nordic countries offer a unique framework in their well-established register systems, personal social security numbers for each citizen, reasonably similar cultural background and long tradition of cooperation among themselves. Harmonising the registers of the Nordic countries would lead to a population base of almost 26 million which provides a solid basis for multiple types of research of high international scientific value and could result in great benefits for society at large. However, cross-border utilisation of these research infrastructures is difficult today due to legal, ethical, technical and organisational constraints. These must be overcome before a Nordic register-based research infrastructure can be established.

Although it is entirely possible to carry out high-calibre scientific research through innovative use of data from existing registers alone, there is vast, untapped potential in the combination of these data sources with e.g. data from biological samples stored in biobanks, quality registers and databases created for research purposes in the behavioural, medical and social sciences. It may also be of great interest to combine official register data with data produced in clinical trials, including pharmaceutical research, other medical research and behavioural interventions (e.g. diet and/or physical activity), and survey data.

While there are obvious benefits, for example in relation to public health, it is imperative that the personal integrity of the individual is not compromised when excavating this goldmine. This is also important for maintaining public trust in research using registers. The years of experience of the Nordic countries in avoiding unwanted disclosure of sensitive information, together with the available technical means of securing data, will undoubtedly ensure that personal integrity is safeguarded.

Nordic register-based research has the potential to attract international interest and to enable the Nordic research community to take the international lead in this field. At present there is a window of opportunity for utilising these data sources at the Nordic level, but this competitive advantage will dissipate, or disappear entirely, if we do not act quickly.

2. Challenges and opportunities for Nordic research cooperation

HUNT Biobank, Norway. Photo: NTNU

2. Challenges and opportunities for Nordic research cooperation

"From the researchers' perspective what is needed is the possibility of mining, analysing and combining data from different sources, including from different countries, and the ability to exchange and collaborate in international research settings while using these data".

– Marjut Salokannel (August 2012)

The starting point of the NORIA-net on Registers and Biobanks (NRB) working group was to critically read, discuss and draw conclusions from the report "Reinforced Nordic collaboration on data resources", TemaNord 2012:514. The report describes the challenges and opportunities related to expanded cooperation on databases and registers using six broad perspectives:

The *political perspective:* issues arising at the political level comprise a "meta perspective" that is relevant, and crucial, for the remaining five perspectives.

The organisational perspective: challenges at the organisational level for Nordic register and database collaboration.

The legal perspective: laws and regulations at the national and EU level of relevance to Nordic collaboration.

The financial perspective: How can increased Nordic register and database collaboration be motivated from a financial perspective? What are the economic challenges?

The ethical perspective: challenges related primarily to the Nordic countries' moral and ethical framework, which is often closely linked to the specific features of each Nordic culture and society. This perspective mainly focuses on register-based research and biobanks.

The technical perspective: challenges that have to be solved at the technical level to support enhanced Nordic database collaboration, such as technology for secure access and federated databases.

The main organisations responsible for register-based data (health registries and bureaus of statistics) in the Nordic countries are:

Denmark: Statens Serum Institut (SSI), Statistics Denmark
Norway: The Norwegian Institute of Public Health (NIPH), Statistics Norway
Sweden: The National Board of Health and Welfare (Socialstyrelsen), Statistics Sweden
Finland: The National Institute for Health and Welfare (THL), Statistics Finland
Iceland: The Directorate of Health

Of the above perspectives, the NRB identified three as being of core importance that could be harmonised at the Nordic level, thereby facilitating cross-border research. These were the legal perspective (related to EU legislation on data protection), the organisational perspective (collaboration between the national bureaus of statistics and between the bureaus and researchers), and the ethical perspective. The NRB's recommendations also encompass research financing.

2.1 The legal perspective

One of the NRB's starting points was the fact that the European Commission had published a proposal for the new General Data Protection Regulation[1] in January 2012, which, after being approved, would be directly applicable in all the Member States. The proposed reform of data protection legislation is based on the principles of protecting personal data as a fundamental right of citizens while at the same time securing the free flow of personal data within the Community as a common good. These principles are well-suited to the goals of the NRB.

The proposed regulation permits the use of personal data for research purposes under following conditions:

I) With the consent of the individual participant (i.e. data subject) for specific research purposes;

II) Without the consent of the individual participant, when processing is necessary for the purposes of scientific research according to following principles:

- personal data should primarily be processed anonymously;
- if the purpose of the research cannot be fulfilled by processing anonymous data and the data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information (as long as the purpose of the research can be fulfilled in this manner).

In other words, if research data cannot be processed with the consent of the individual participant, which would be the case e.g. with regard to register-based data in public registers, it may be processed anonymously or in a key-coded form presupposing that the re-identification of individuals is prevented. According to the national data protection authorities, this could be done e.g. by using two-way encrypted data with the key securely in the hands of a third trusted organisation.

The Commission's original proposal for processing personal data for research purposes did not distinguish between processing of sensitive personal data on the one hand and non-sensitive data on the other hand, even though as a general rule the processing of sensitive personal data was prohibited. This was addressed in a compromise proposal for the data protection regulation issued by the European Parliament (20 October 2013), in which processing of personal data for research is subject to more stringent conditions. The proposal was later approved by the Plenary of the Parliament and became Parliament's legislative proposal.[2] The processing of health data in particular is subject to stricter processing conditions.

According to Parliament's legislative resolution, health data may in principle only be used with the consent of the data subject. However, when the processing of medical data is carried out **exclusively for public health purposes of scientific research, the consent of the data subject may be given for one or more specific and similar researches. The data subject can withdraw consent at any time.** For the purpose of consenting to participation in scientific research activities in clinical trials, the relevant provisions of Directive 2001/20/EC apply. From 2016 onward the new Regulation on clinical trials will be applicable in this respect (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).

If it is not possible to acquire consent from the data subjects for the research in question, health data may be used anonymously if the scientific research is of high public interest. Moreover, if using ano-

1 Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) COM/2012/011 final.

2 Report on the proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (COM(2012)0011 – C7-0025/2012 – 2012/0011(COD)), 22 November 2013. Committee on Civil Liberties, Justice and Home Affairs, Rapporteur Jan-Philipp Albrecht. Protection of individuals with regard to the processing of personal data, European Parliament legislative resolution of 12 March 2014 on the proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (COM(2012)0011 – C7-0025/2012 – 2012/0011(COD)). http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2014-0212

nymised data is not possible for the purposes of the research, Parliament's resolution allows the processing of health data for research purposes with pseudonymised data. This presupposes that **the data is pseudonymised under the highest technical standards, and all necessary measures have been taken to prevent unwarranted re-identification of the data subjects.** The definition of public interest in health research has been left to the Commission and the Member States to decide.

The NRB wishes to highlight the opportunities that **this would provide for the Nordic countries to harmonise their national legislation on the use of health data for research purposes.** Harmonisation of the prerequisites for using combined register-based data in health research across Nordic national borders for the public good would greatly increase the scientific potential and societal impact of such research. Pooling resources at the Nordic level would also facilitate comparative studies of health and social factors.

To conclude, with regard to the still ongoing negotiations to achieve a common updated data protection framework at the EU level, it seems safe to presume at this stage that if any one of the existing proposals for regulating processing of personal data for research purposes is approved even in a slightly amended form, it will allow the processing of data in an anonymous or pseudonymous form under the highest technological security standards. With regard to cross-border use of register-based data in the Nordic countries this would mean that **if we are able to agree upon common standards for anonymising or pseudonymising data for cross-border research purposes, we could achieve research collaboration with secure sharing of data at the Nordic level**.

The working group proposes that the Nordic countries develop common procedures for sharing register-based microdata across their borders. This means that **with regard to further defining certain exceptions relating to scientific research under the general data protection law, the final national legislation permitted under the data protection regulation will require approximation at the Nordic level**.

Moreover, the Nordic copyright laws contain elements that may pose additional obstacles with regard to cross-border use of register data even if the data would otherwise be re-utilisable for research purposes under freedom of information and data protection legislation. This is particularly relevant in relation to new and emerging technological methods for using different data analysis tools to mine large masses of data, e.g. in public registers. These issues are also currently on the agenda for reforming European copyright legislation, which is why the NRB proposes the further investigation of common Nordic solutions.

2.1.1 Conclusions

Obtaining the full benefit from existing Nordic register data presupposes that register data and other research data may be combined and used across borders in an efficient and secure manner. To a large extent this should already be possible under current legislation, but in practice it has proven to be extremely cumbersome and time-consuming. If the proposed harmonisation of EU data protection legislation is approved, it could provide an even better basis for using register-based data for research purposes across borders. In principle, such research could be carried out either with the consent of the data subjects or by using anonymised or pseudonymised data. The working group recommends streamlining the anonymisation/pseudonymisation procedures for personal data and introducing similar procedures at least with respect to pan-Nordic research projects in all the Nordic countries. This would allow for quality control of data validity.

The working group also proposes the further investigation of the potential impact of Nordic copyright laws and data protection laws on using data analysis tools for data and text mining of existing registers and other materials. This is particularly relevant with regard to research involving Big Data.

2.2 The ethical perspective

Typically, a research project using register information, once funded, is first subject to ethical vetting, and if approved, submits an application for access to the information to the national public agency in charge of the registry/registries. Access to and use of the information is further subject to regulation by an overarching authority that has the general responsibility for protection of privacy and registration of information that can be traced to individuals.

There are several important ethical challenges in using personal information from databases and registers for research purposes; these are related, in particular, to privacy and the protection of personal information.

As already discussed in Section 2.1, the EU data protection legislation currently being formulated permits the use of personal data for research purposes either when consent from the participating individual has been obtained, or without consent, provided that the data are processed anonymously or in a key-coded form. Ethical questions about practices and procedures arise in both cases. In this context, a crucial question is how the act of giving consent is defined in terms of data protection and in which situations data can be processed anonymously. Moreover, the parameters for secure pseudonymous processing of personal data must be clearly defined.

One obstacle to Nordic collaboration is that projects linking data from several Nordic countries require an ethical review in each country. Not only is this cumbersome for researchers, but it may also make cooperation among the Nordic countries more difficult, as individual ethics committees may interpret ethical principles differently, for instance, in relation to informed consent procedures.

The issue of consent has been widely discussed in the context of biobanks. Because databases are tools for future research, it is impossible when collecting data or samples to inform participants of what types of research will be conducted or how the information may be used at a later point in time. Several different forms of consent have been introduced to meet these challenges, including broad consent, open consent and dynamic consent. In some Nordic countries, broad consent has already become the recruitment standard for biobanks (Iceland), while in other countries (Sweden) it is not regarded as appropriate in terms of data protection. For data sharing at the Nordic level to be possible, a shared understanding of such ethical terms among the Nordic countries is needed. It should, however, be kept in mind that defining the prerequisites for consent must be done within the framework of European legislation, in particular with regard to data protection and clinical trials as well as the EU Charter of Fundamental Rights.

At the Rosenbad conference in March 2013, panellists representing ethics committees were asked whether procedures for joint Nordic research could be simplified so that an evaluation by one ethics committee in a single Nordic country would suffice for all the Nordic countries. In other words, an ethical review would be valid across borders. This would require harmonisation of national laws and regulations, as well as a shared understanding of relevant ethical principles. In particular, it would mean analysing the extent to which the 2004 Swedish act relating to ethical evaluation of research would have to be amended in order to permit the mutual recognition of decisions taken by ethics committees in other Nordic countries. Nevertheless, the panellists saw great opportunities for further cooperation and harmonisation between the Nordic countries.

The NRB recommends further investigating how to achieve a system in which a research project would require only a single ethical review by the ethics committee in the country of the Principal Investigator and in which the other ethics committees involved would be informed of the decision and possibly given the opportunity to disagree. Furthermore, such an investigation should map the various ethical procedures within each country to identify their similarities and differences. Further dialogue between ethics committees should therefore be encouraged. The implementation of the new EU regulation on data protection may provide the ethics committees with a unique opportunity to develop a shared understanding of ethical principles on the issue of data sharing at the Nordic level. Therefore, work on ethical principles must be continued at the Nordic level in the near future.

2.2.1 Conclusions

The NRB strongly recommends putting ethics issues on the agenda at a joint meeting of the central authorities responsible for ethical review of research in the Nordic countries. It is important for these authorities to have a shared understanding of how the evaluation procedure can be streamlined and further cooperation between Nordic countries facilitated. The ultimate aim is that approval in one country will be valid in the other countries in cases of cross-border research cooperation. An opportunity for the other countries to opt out should, however, be maintained. It is recommended that NordForsk provides a platform for facilitating discussion between the national ethics committees in the different Nordic countries.

2.3 The organisational perspective: national bureaus of statistics

The national bureaus of statistics play a central role in producing and coordinating data for statistics. Their registers are primarily used for surveillance and policy, rather than scientific research per se. However, the data are immensely valuable for research as well, e.g. in the health and social sciences, and are widely used by researchers. Moreover, the data can be combined with biological data derived from clinical trials and biobanks. Facilitating research is stipulated as one of the main purposes of European statistics legislation. In the recent amendment of statistics legislation in Finland, for instance, supporting research was included as one of the tasks of Statistics Finland, and Statistics Denmark has provided support to researchers who use data found in its computers for several years.

The role of data sharing among the Nordic bureaus of statistics was discussed at the Rosenbad meeting. It was evident that receiving data for research from other bureaus and being responsible for processing the material would not be a major problem. However, sending identifiable datasets to a bureau in another country, and thus handing over control of the material, would be more or less out of the question for reasons of integrity. In fact, fully identifiable data are very seldom needed for research, and this principle is likely to be of importance in maintaining public trust in the use of registers.

This peculiar situation was also noted at the Rosenbad meeting by representatives of the bureaus of statistics themselves. As a consequence, a Nordic task force group was established in the autumn of 2013 to further elaborate on this issue.

Another issue already mentioned in the section on the legal perspective (Section 2.1) was whether the bureaus of statistics could be used in the process of anonymising or pseudonymising data. The working group proposes that the statistics authority of the country of the research organisation with which the Principal Investigator is affiliated should be in charge of the anonymisation or pseudonymisation of the data in cases where statistical microdata from different organisations must be merged and linked together.

After anonymisation/pseudonymisation, the statistics authority could deliver the data to the Principal Investigator for use in the research project. The NRB acknowledges that this may require some additional resources at the bureaus of statistics.

Alternatively, there could be a specific national organisation in charge of anonymisation or pseudonymisation of register data and other personal data for use in scientific research, or each organisation could carry out the anonymisation/pseudonymisation itself and the combining of data from the various organisations would be handled on a case-by-case basis.

One example of bilateral cooperation is the transregional register created for the purpose of analysing migration flows between Denmark and Sweden (Report of the Expert Group for International Collaboration on Microdata Access, OECD, Paris, July 2014, #160 page 85). In this case, data are also provided at the personal level. A serial number is assigned to the microdata, which are anonymised prior to potential release for research purposes. The conditions and possibilities for the release of data to supplement existing research registers or establish new registers will be assessed in a separate procedure.

A third issue is related to the harmonisation of data administered by the national bureaus of statistics. The joint use of these registers would be greatly enhanced if the data were collected and classified using compatible procedures and categories. This is a challenging issue, however, as long-term national follow-up may be based on data collected in specific ways, and changing the data collection procedures could jeopardise possibilities for studying trends and co-variation in trends. However, it may be possible to set up metadata libraries instead that would allow for translation across countries.

2.3.1 Conclusions

The bureaus of statistics are in a key position to enhance the use of data for research across Nordic borders. The NRB recognises that it cannot impose any changes on the internal principles of the bureaus. However, given the important role of statistics data, and consequently of the statistics authorities, in register-based research, the working group proposes that the Nordic bureaus of statistics become actively involved in facilitating and promoting secure cross-border use of data. NordForsk should play a role in facilitating this work, if necessary. The working group emphasises that taking a qualitative step in research collaboration at the Nordic level will require the adoption of common measures with regard to the anonymisation/pseudonymisation of data as well as the harmonisation of data collection or building of metadata libraries.

3./4. Recommendations

Preacher's Pulpit. Lysefjord, Norway. Photo: Brykaylo Yuriy

3. Recommendations from the concluding workshop on health and welfare with regard to Nordic Opportunities for Research Cooperation on Biobanks, Databases, Registers and Interventional Research

On 27–28 November 2013, Nordic data sharing was discussed at the conference "Joint Nordic Focus on Research Infrastructures – Looking to the Future". The conference was organised under the Swedish Presidency of the Nordic Council of Ministers (NCM) 2013 by the Swedish Ministry of Education and Research, the Swedish Research Council, the NCM and NordForsk, and targeted policy-makers, researchers and infrastructure managers. During the thematic session on health and welfare, issues related to the work of the NRB were discussed. The following actions were agreed on in order to increase Nordic cooperation on biobanks, databases, registers and interventional research:

- Simplify Nordic research support operations carried out by the Nordic bureaus of statistics, national health registry institutes and other registry-hosting bodies.
- Set up procedures for mutual recognition of ethical review permissions between the Nordic countries.
- Support approximation of Nordic legislation and practices for using personal data in cross-border research.
- Support the development of technical solutions enabling secure transfer, storage and access to research data across borders, possibly through the Nordic e-Infrastructure Collaboration (NeIC).
- Investigate the possibility of creating a unified data sharing facility in each country, such as the Danish solution for health data.
- Launch funding schemes for research pilots and training programmes aimed at using joint Nordic data sources.
- Establish a Nordic initiative to support, monitor and develop register-based research.

4. Recommendations to the NordForsk Board

Having concluded its work, the NORIA-net on Registers and Biobanks working group makes the following six recommendations to the NordForsk Board:

1. NordForsk should provide a cooperation platform for the Nordic bureaus of statistics, national health registry institutes and other registry-hosting bodies. This platform should facilitate research support operations in order to increase joint Nordic research. Discussion platforms for different stakeholders should also be supported, when relevant.

2. NordForsk should investigate possibilities for developing procedures for mutual recognition of ethical review permissions between the Nordic countries, including models for informed consent. This will require political consideration and should be carried out in dialogue with the Nordic Council of Ministers.

3. NordForsk should actively follow, and, if necessary, influence the ongoing revision of European legislation targeting data protection, clinical trials and copyright legislation, in particular in relation to data sharing and with a view to drawing the full benefit of new research technologies, such as text and data mining. This may require political consideration and follow-up by the Nordic Council of Ministers.

4. NordForsk should establish a small strategic expert group responsible for these processes, initially for the 2014–2016 period. The group should possess the relevant expertise and have the support of relevant Nordic stakeholder groups. It should report to the NordForsk Board.

5. As a follow-up to recommendations one to three, NordForsk should establish a research programme to pilot the joint Nordic use of registers.

   The programme should fund Nordic pilot projects using joint Nordic register data sources within the field of health and wellbeing. The pilot projects should be monitored and evaluated in order to further analyse possibilities, impediments and challenges to answering concrete research questions using register-based data. This will be done in the context of evolving conditions at the EU level, making a pilot initiative even more important.

   The pilots should combine different types of registers (social, e.g., education, labour market, migration, etc., and health, e.g. patient registers, prescription registers, cancer, biobanks, etc.) and complement the BBMRI Nordic Pilot on colon cancer (http://www.nordforsk.org/en/programmes/prosjekter/joint-nordic-biobank-research-infrastructure). The pilots should be awarded funding on a competitive basis with international peer-review assessment, and should tentatively run for a period of three years (2015–2017).

6. Future vision: A Nordic Centre for Register-based Research

   The aim of a Nordic Centre for Register-based Research would be to follow up the issues identified in this report on an ongoing basis, and to facilitate cooperation between the bureaus of statistics, ethics committees and other relevant agencies in the Nordic countries. The centre should maintain information on register data and provide support to researchers using data sources from two or more Nordic countries, as well as promote links to international initiatives (outside the Nordic countries).

   The Nordic Centre for Register-based Research could be coordinated by NordForsk and have an organisation tentatively modelled on the Nordic eInfrastructure collaboration (NeIC), i.e. based on Nordic networks of researchers. The centre should be up and running no later than 2016/2017.

Annex 1
Report from Rosenbad meeting

Photo: Shutterstock/kentoh

Annex 1
Report from Rosenbad meeting

Summary of "Nordic Expert Meeting. Responsible Data-sharing Across Borders"

Rosenbad Conference Centre, Stockholm, 5 March 2013
Organiser: NordForsk in collaboration with the Swedish Presidency of the Nordic Council of Ministers 2013

Introduction and background

Olivia Wigzell, Deputy Director-General, Swedish Ministry of Health and Social Affairs
Anders Geertsen, Head of Department, Nordic Council of Ministers
Gunnel Gustafsson, Director, NordForsk

Wigzell, Geertsen and Gustafsson described the starting points for the expert meeting in their opening remarks: the population registers, research databases and biobanks of the Nordic countries constitute a unique resource for research. They are extensive and of high quality, and the social security identification code makes it technically easy to combine data from different sources. These resources currently make up five relatively isolated national systems, with very limited opportunities to include data from other countries. In many cases, however, it would be very valuable for research to be able to combine data from several or all Nordic countries. One of the reasons for this is the value of a larger population basis – the total population in the Nordic region is approximately 25 million – which is a critical factor in many cases, such as for research into unusual diagnoses and side effects of medicinal products. Studies at the Nordic level also give researchers the opportunity to study both the similarities and the differences between the five Nordic varieties of the welfare system.

Geertsen highlighted the interest which the Nordic welfare model is attracting internationally – in the eyes of the rest of the world, this is a model that succeeds in combining welfare and economic growth, security and competitiveness. At the same time, those of us who live in the Nordic region can see that our welfare model is coming under pressure. We live longer, have higher expectations for what our public services can provide and we are also struggling with other structural problems, such as youth unemployment. All of this makes the Nordic welfare model extremely interesting as a field of research, both for the rest of the world and for the Nordic countries themselves.

Gustafsson presented the NordForsk working group, NORIA-net on Registers and Biobanks, which has been looking into the issues of sharing registry data, biobanks and research databases across borders in the Nordic region since 2011, and that today's expert meeting is giving key input for this task. She also stated that an important process in the EU is currently underway to formulate a new regulation for protection of personal data.

Using Nordic Registers in Concert – A World-class Research Tool

Jørn Olsen, Professor of Epidemiology and Social Medicine, Aarhus University

There are larger registers in other parts of the world, but the diversity of the registers in the Nordic region, with the breadth of both socio-economic and clinical data as well as time series spanning over two to four decades (sometimes significantly more), make the Nordic registers a unique resource for research, which, according to Jørn Olsen, has not been utilised to a sufficient extent.

The ability of researchers to use the material is regulated by more than just legislation. In many cases, the government agency maintaining the registry has formulated its own rules which additionally limit the room to manoeuvre of researchers, said Olsen. He also pointed out that the integrity discussion on this subject at the European level will be difficult to understand from a Nordic perspective unless one gives due consideration to the fact that register data has been misused in the past. However, he emphasised that it was government authorities, not researchers, who misused the data.

Register-based research, according to Olsen, has special importance in situations where:

1. data from other sources is difficult to obtain.
2. data from other sources risks having a bias.
3. the research involves unusual conditions and is therefore in need of an especially large corpus.

Among the examples Olsen gave was a study of the connection between vasectomies and the risk of testicular cancer. The World Health Organization (WHO) had received indications from researchers that such a connection did exist, but a Danish register study was able to refute this. This was very important news for the WHO's programme for family planning at the time. Another example with great international significance is the alleged link between the measles vaccine and the risk of autism, where Nordic register studies were among the first to disprove the connection.

Register data may also be used to compare healthcare results between the Nordic countries, and thus provide a basis for innovations for improvement.

Olsen also stated that making joint Nordic data available will require similar laws and rules, better documentation and information concerning which data is available, as well as a joint centre/joint technical platform to be able to offer the data and information to researchers at a distance as well.

Nordic Data-sharing Framework – A Legal Perspective

Marjut Salokannel, Lawyer, Independent Consultant

Marjut Salokannel gave an account of the legal situation with regard to research access to register data in Europe. The current EU directive on the protection of personal data is from 1995 and the process of developing updated legislation in the form of an EU regulation is fully underway. A decision by the European Parliament is expected at the end of June 2013 and the final version of the regulation should be adopted by summer 2014. Eighteen months after having been approved, it will enter into force as applicable law in all of the member states.

The Commission presented an initial proposal for the new data protection regulation in January 2012. Its provisions relating to the use of data for research purposes were criticised, among other things, for not differentiating between non-sensitive and sensitive personal data. A new proposal from the European Parliament called the "Albrecht proposal" was then formulated with stronger protection for sensitive personal data and the personal data of children when used for research purposes, in particular for commercial research.

The Albrecht proposal will not necessarily change the prevailing practices for the Nordic countries, according to Marjut Salokannel. The exceptions that currently permit processing of personal data for research under data protection law will also be possible to implement under national law in the future. What is most important for the establishment of a joint Nordic research area in register and biobank research is what the Nordic countries are doing on the home front, she said, and presented a number of proposals from NordForsk's register working group:

1. Applicable Nordic laws relating to data sharing would be synchronised to the extent that would make it possible to share and combine data within a research project across registers and across borders (data protection, ethical review, statistics, biobank etc.).

2. Ethical permissions would be mutually recognised as valid throughout the Nordic countries.

3. Only one prior authorisation of the data protection supervisor would be required for each research project.

4. Each country would ensure that research data is properly anonymised or pseudonymised by the registry-hosting organisation itself or other competent body, according to the latest technical standards.

   Pseudonymisation would mean two way encryption of data; a key with a trusted organisation is to be determined at the national level.

5. If statistical microdata needs to be linked with other register-based data or other data and across borders, the statistics authority of the country of the research organisation with which the principal investigator is affiliated would be in charge of the anonymisation or pseudonymisation of the data.

6. After anonymisation/pseudonymisation of the data, the statistics authority would deliver the data to the principal investigator for utilisation in the research project.

7. The principal investigator may deliver the key-coded data sets to other researchers, including to those residing in other Nordic countries. All researchers would be subject to strict confidentiality when using the data.

Salokannel stressed that the intention to create a joint Nordic research area for register-based research and data sharing is supported by Article 179 of the Treaty on the Functioning of the European Union, which states that the Union is to support better opportunities for research by facilitating research across national borders and eliminating, among other things, legal obstacles to such research.

Salokannel proposed that the work on developing a common Nordic platform for sharing data should be led by NordForsk.

Panel I – The Bureau of Statistics Perspective

Denmark: Lars Thygesen, Statistics Denmark
Finland: Päivi Hämäläinen, National Institute for Health and Welfare
Iceland: –
Norway: Bjørn Henrichsen, Norwegian Social Science Data Services
Sweden: Stefan Lundgren, Statistics Sweden
Introduction by Juni Palmgren, Swedish Research Council, member of the NordForsk register working group
Moderator for all panel discussions: Bengt Westerberg

Palmgren asked for the panel's opinion on a scenario in which personal data including identifiers are sent from several countries to Statistics Denmark, for example, to be linked together. Lars Thygesen gave a clear-cut answer: Receiving data from others and being responsible for processing the material would not be a problem at all. However, sending data sets to a bureau of statistics in another country, thus handing over control of the material; no, that would be out of the question. The main reason for this restrictiveness is to maintain the public's high level of confidence in Statistics Denmark, he explained.

Stefan Lundgren confirmed that Statistics Sweden sees the problem in the same light: happy to receive, but out of the question to send off data before it has been anonymised/pseudonymised. Maintaining control over data is necessary, both for preserving the confidence of the public and for meeting international obligations under agreements with the UN and the EU, he stated.

Bjørn Henrichsen was of the opinion that, in spite of everything, the systems could perhaps be designed differently, with some form of common platform created to allow data to be shared across borders, with such good monitoring that there is no risk of compromising the overall confidence in the protection of privacy of the system.

In Finland, Päivi Hämäläinen explained, one complication is that the processing of data is governed by two different types of legislation, depending on the context.

With regard to the material linked to biobanks, Juni Palmgren noted that there can be such extensive sets of data that it is not realistic to consider processing them in the server environment of a bureau of statistics. This type of research requires solutions where biobank data and the bureau's registry can be combined in a way that safeguards privacy in another environment while ensuring high technical performance.

Comments from the audience:

- Being on the cutting edge in Europe is not necessarily the same thing as being on the cutting edge globally. Don't forget to follow developments in countries such as Australia and Japan.

- The quality of register data varies. Common Nordic standards for data collection are needed.

Panel II – Data Inspection Board Perspective

Denmark: Ellen Aagaard Nøhr, Aarhus University
Finland: Reijo Aarnio, Data Protection Ombudsman
Iceland: Þórður Sveinsson, Data Protection Authority
Norway: -
Sweden: Erik Janzon, Data Inspection Board
Introduction by Eskil Wadensjö, Swedish Institute for Social Research (SOFI), Member of the NordForsk register working group

Bengt Westerberg began with a question for the panel: have there been incidents where register data research has infringed on the privacy of individuals, causing grievance?

Þórður Sveinsson mentioned a research project concerning mental illness, which included an email questionnaire. Due to a technical error, all of the recipients of that group mailing were visible to all of the other recipients. Ellen Aagaard Nøhr spoke of a case where Danish researchers included Excel files with personal data in a PowerPoint presentation, and another case where personal data from a cancer study was actually posted publicly on the internet. Reijo Aarnio explained that researchers commonly do not want to delete the material after the period of their permit expires. Erik Janzon remarked that many of the complaints received by the Data Inspection Board concern research regarding children, in school for example, and that there can be surprisingly little knowledge of how consent is to be obtained, even at major universities.

The panel also discussed the wide range of different types of actors involved in research, and the extent to which it is possible to regulate which people and organisations are welcome to use a platform for joint Nordic register-based research. An equal treatment requirement applies in the EU. It is also conceivable that commercial research companies, for example, from China, will see the potential and want to use the register.

Comments from the audience:

- Researchers at Danish research institutions can deposit data for long-term storage with the Danish Data Archive instead of deleting the data after completion of the research project. It is then also possible to reactivate this data for new research at a later stage.

Panel III – Ethical Committee Perspective

Denmark: Jørn Olsen, Aarhus University
Finland: Markus Perola, National Institute for Health and Welfare
Iceland: Björn Rúnar Lúdviksson, Landspitali University Hospital and until recently National Bioethics Committee
Norway: Bjørn Hvinden, National Committee for Research Ethics in the Social Sciences and the Humanities, and Norwegian Social Research, NOVA.
Sweden: Anders Brändström, Central Ethical Review Board, and Umeå University
Introduction by Salvör Nordal, Centre for Ethics, University of Iceland, member of the NordForsk register working group

Salvör Nordal began by describing different principles for how researchers obtain consent from the persons involved. For several decades, informed consent in advance has been the golden rule in all of the Nordic countries. However, different conditions in new fields of research have also led to other types of consent. "Broad consent" has become the standard for biobank recruitment, and "open consent" has been proposed as an appropriate principle for genome sequencing. Another relatively new proposal is "dynamic consent", which means that researchers maintain contact with the affected persons over a long period of time and obtain new consent whenever needed.

Bjørn Hvinden observed that the act of giving consent should be separate from clinical care decisions. Should the patient perceive the consent as a prerequisite for treatment, it cannot be regarded as freely given. People hesitate to say no to the people that have the patient's life in their hands.

The panel agreed that different forms of consent are appropriate in different situations. Demanding informed consent is inappropriate right off the bat in certain situations; for example, it can cause grief and anxiety, or repeated new queries may be perceived as tiresome and annoying. Anders Brändström described an example where, instead of contacting people directly, a university held a public press conference about a research project (concerning cervical cancer) to give the people involved a chance to withdraw from the study.

Jørn Olsen took the view that current practice for informed consent, which originated in the 1964 Declaration of Helsinki, has been appropriate for a long time, but that research and society now need to rethink it, because conditions have changed radically.

Björn Rúnar Lúdviksson stated that if research activities are to maintain the public's confidence, then the participants/society need to get understandable feedback about the results of the research. He felt that research, to a large extent, fails to do that at this time.

The distinction between ethical competence and scientific competence was also discussed. The task of an ethical committee may be to safeguard both privacy and good science. On the other hand, it has been the case that ethical committees have opinions on scientific quality without actually being competent to judge the matter.

Can processes for joint Nordic research be simplified so that an ethical review in one country can be valid in all of the Nordic countries? Yes, the panel participants saw great opportunities for that, on the condition that legislation is harmonised.

Comments from the audience:

- One key trend in other scientific disciplines is the development of research based on very large sets of data – often with very open questions. Terms such as "data deluge" and "Fourth paradigm of science" are used to describe this trend. With the current principles for consent and ethical review, register and biobank research seems to be missing out on the opportunities offered by this type of research.

Professor Juni Palmgren introduced the panel discussion on the bureau of statistics perspective. Photo: NordForsk

Conclusions

Bengt Westerberg, Moderator, Government Commissioner
Gunnel Gustafsson, Director, NordForsk

Bengt Westerberg informed the audience about his assignment from the Swedish Government to review regulations for Swedish register-based research. The goal is to find ways to create better access to microdata for researchers without jeopardising personal privacy. Westerberg's commission is to submit its final report to the Government by 30 June 2014.

Gunnel Gustafsson concluded that the day's discussions had been successful in shedding light on the challenges and opportunities associated with joint Nordic register research. She also remarked that she is looking forward to more discussion on combining data concerning health and social aspects. The real progress for research will come when health and social issues are addressed together, she said.

Gustafsson announced that the NordForsk register working group will be submitting a proposal for measures to be taken to NordForsk board towards the end of the year.

She ended by giving special thanks to Erland Hjelmquist, Mikael Fogelholm and Maria Nilsson for their work in conjunction with the expert meeting.

– Text by Anders Nilsson, science journalist

Annex 2
Country study (overview of the legal frameworks of Denmark, Finland, Norway and Sweden)

Illustration: Shutterstock/shooarts

Annex 2
Country study (overview of the legal frameworks of Denmark, Finland, Norway and Sweden)

Marjut Salokannel, Docent, LL.D, independent consultant in Information law
23 April 2014

NordForsk: Country studies

AN OVERVIEW OF THE CURRENT LEGAL SITUATION WITH REGARD TO SHARING MICRODATA FROM PUBLICLY-FUNDED POPULATION-BASED REGISTERS ACROSS BORDERS IN THE NORDIC COUNTRIES

Nordic countries possess invaluable reserves of register data in their public sector registries, which have been compiled during the 20th and 21st centuries on a systematic basis. These registers are built upon roughly the same basic principles in all the Nordic countries, and they would constitute an immense pool of research data if they could be utilised to their full extent across borders and at the population scale.

The following presents an analysis of how personal data can be used for research purposes as well as of how personal data recorded in publicly-funded population-based registers can be used for research purposes across borders in the Nordic countries and combined with other data from similar public registers in other Nordic countries, with the exception of Iceland. An overview of how it is possible to combine the register data with other data, such as biobank data, is also provided. The use of patient records for research purposes is not covered in this report.[3]

Denmark

1. Legal framework

In Denmark, the use of personal data for research purposes is governed at the general level by the Act on Processing of Personal Data (429/2000), hereafter referred to as the Danish DPA. According to the act, processing of pre-existing data carried out exclusively for scientific purposes is not considered to be incompatible with the purposes for which the data were collected. (Section 5.2) Processing of non-sensitive data for scientific research is possible under the provision of the law allowing processing of personal data if necessary for the performance of a task carried out in the public interest. (Section 6(5))[4]

The Danish DPA allows processing of sensitive data for reasons of substantial public interest. This requires prior authorisation from the supervisory authority (Danish Data Protection Agency). The processing may be made subject to specific conditions. (Section 7.7)

The act permits the processing of sensitive data for scientific research if the processing takes place for the sole purpose of carrying out statistical or scientific studies of significant public importance and

3 This report was completed in April 2013, and thus does not include any legislative or other changes that have taken place since then.

4 Cf. Hartlev, Mette in Beyleveld, Deryck, ed. Implementation of the Data Protection Directive in Relation to Medical Research in Europe, Ashgate, 2004, p. 64.

if such processing is necessary in order to carry out these studies. Sensitive data which has been processed for scientific research under this provision may not subsequently be processed for other than statistical or scientific purposes. The same shall apply to processing of non-sensitive data carried out solely for statistical or scientific purposes. The data covered may only be disclosed to a third party with prior authorisation from the supervisory authority. The supervisory authority may lay down specific conditions concerning the disclosure. (Section 10)

Processing of health data in clinical trials and comparable research projects involving interventional studies is subject to a specific act[5], not Section 10 of the Danish DPA. However, clinical studies must also comply with the provisions of DPA. The processing of personal health-related data in such studies is subject to statutory ethical review. Clinical studies are also governed by other legislation (e.g. the Danish Medicines Act and the Act on Medical Devices).

Official authorities may process data with identification numbers in order to achieve unambiguous identification or as file numbers. Private persons and companies may process data in which identification numbers are included if the processing is carried out solely for scientific or statistical purposes. An identification number may not be made public without explicit consent. (Section 11, Danish DPA)

2. Biobanks under Danish law

There is no specific legislation relating to biobanks in Denmark; however, the Danish DPA, legislation on scientific ethics committees and ethical handling of health science research, and the Health Act are all applicable to biobanks. Biobanks are defined as structured collections of human biological material that are accessible in compliance with certain criteria and in which information contained in the biological material can be linked to individual persons.[6] In principle, under the DPA, the personal data contained in biobanks are treated like any other personal data stored in registries. All collections of human data must be registered with and approved by the Danish Data Protection Agency.[7]

Biobanks may be established for a specific research purpose. A general research biobank is not permitted under the law. The establishment of a biobank requires only the permission of the Data Protection Agency; however, a separate permission from the ethics committees may be needed for a specific research project.

3. Access to Danish register data in practice

In October 2012 the Danish Government published the Danish Basic Register Roadmap in which it announced its plans to release all government-produced raw data for re-use free of charge in the near future.[8] Since then, Danish geodata and company data have already been released for free re-use. This initial release does not cover any data subject to data protection laws, but the Government plans to investigate how the registers that include personal data can be better utilised.

With regard to health data, several steps have already been taken in that direction. In the beginning of 2012 it was decided in Denmark that all health-related documents under the domain of the Ministry of Health and Social Affairs would be consolidated under a single institution. Consequently, all health data, the Danish National Biobank, national infectious disease control and national health IT systems were all grouped together within the Statens Serum Institut (SSI) (the National Serum Institute). This will enable researchers, for example, to combine data from the National Biobank with register-based data from SSI. SSI can also combine biobank data with microdata from Statistics Denmark. SSI offers researchers access to vast amounts of health data through a research support unit.[9]

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5 Lov om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter, 593/2011.

6 For further details, see: http://www.datatilsynet.dk/english/health-research-and-statistics-projects/biobanks-are-covered-by-the-act-on-processing-of-personal-data/, accessed 16 April 2014.

7 Cf. Kyvik, Kirsten. Danish biobank legislation, a simple approach?, Norsk Epidemiologi 2012, 21(2): 161-162.

8 Available in English at: http://epsiplatform.eu/content/danish-basic-registries-roadmap.

9 http://www.ssi.dk/Sundhedsdataogit/Forskerservice.aspx

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The purpose of the National Health Documentation is to cover the entire value chain from raw data and modified data to analysis and production of information and evidence-based data for use by political, clinical and administrative decision-makers as well as researchers.[10]

4. Access to microdata at Statistics Denmark

Statistics Denmark has an online access environment for researchers who need to gain access to the microdata stored in the national registries hosted by Statistics Denmark. Statistics Denmark grants researchers access to de-identified microdata at the person, family, household, workplace and company level under certain conditions. Access is granted only to researchers at pre-approved Danish research institutions or other organisations. These include public research and analysis environments as well as research organisations that, which are part of non-profit foundations.

Statistics Denmark can also grant authorisation to private sector organisations, which have a stable research or analysis environment. These organisations may include non-governmental organisations, consultancy firms and enterprises.

Individuals are not granted authorisation to access data. Foreign researchers are only granted access to data if they are affiliated with a Danish research environment, in which case the Danish research environment must assume full liability on behalf of the non-Danish researcher vis-à-vis Statistics Denmark. This includes appointing a contact person who will act as a liaison between the foreign researcher and Statistics Denmark.

Access to microdata is granted in relation to the research proposal. This means that the researcher can only gain access to the data needed to fulfil the purpose of the research.[11] In their applications, researchers must be able to prove a reasonable relationship between the requested data and the project description. If the research proposal requires population-wide coverage, access may be granted to the totality of the data. Otherwise access will be granted to a sample of the data needed to carry out the proposed research.

Statistics Denmark can link its data to data from other sources, such as the Danish Health and Medicines Authority, as specified in the research project. Linking data from Statistics Denmark to data from other registers or to other data requires the prior approval of the Danish Data Protection Agency.

Access to microdata at Statistics Denmark is given through a research server that is separate from the production network and contains only de-identified information for research purposes. Researchers are given access via an encrypted and secure channel over the Internet after they have signed a confidentiality agreement. Researchers may only access the de-identified data on the research server, and they are not allowed to print out or otherwise remove the data from the server. Only aggregated data in which no identification of persons is possible can be removed from the server. All aggregated research results are stored in a special file and the print-outs are sent to the researcher by e-mail. All e-mails are logged at Statistics Denmark and checked by the Division of Research Services.

10 Strategi for National Sundhedsdokumentation. Statens Serum Institut.

11 The Danish system for access to microdata. Statistics Denmark. June 2012.

Finland

1. General legal framework

In Finland access to public sector information is regulated by the Act on the Openness of Government Activities (621/1999), hereafter referred to as the Finnish FoIA. The way in which personal information can be obtained from public registers is also primarily regulated by the FoIA. (Section 8.4, Personal Data Act) In addition, the basic public registers are subject to specific regulations. This legislation is given precedence, and the general legislation, which in this case is the FoIA and the Personal Data Act (523/1999), hereafter referred to as the PDA, is applied in a complementary manner.

According to Finnish legislation, use of personal data for research purposes must primarily be based on the consent of the research subjects. In cases where obtaining consent is unduly difficult and the research cannot be carried out without using the data, the data can be used without consent, provided that it satisfies the prerequisites set out in the law.[12]

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.

When it is a question of releasing data held by a public authority that is subject to secrecy under 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. Whether this is possible must be decided separately for each case, in which connection also the interests of scientific research must be taken into account of. (Section 28, FoIA)

Once the conditions for handing over data for research purposes are fulfilled in terms of the FoIA, the relevant provisions of the Personal Data Act must then be satisfied. The PDA provides the possibility to use personal data for research purposes without the consent of the data subject, or based on other factors given in the law, under the following conditions:

1. The research cannot be carried out without identifiable personal data and it is difficult to obtain the consent of the 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.
2. The use of the register of personal data is based on a research plan and there is a Principal Investigator or a research group which 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.
3. 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.
4. 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 applies when the processing of personal data is based on sector-specific legislation. (Section 14.2, PDA)

12 Government proposal for the Data Protection Act (HE 96/1998).

The law and the preparatory works of the PDA do not explicitly state whether personal data in public registers can be released with identifying information, such as social security numbers. The preparatory works recognise that cases may arise in which the exact identification of research subjects is necessary. This may be the case, for example, when linking data from different registers or linking register data to patient records.[13] Even in such cases, obtaining individual consent for the use of the identification codes of the research subject is always the starting point. This means that, for example, with regard to research on rare diseases affecting a small number of people residing in the country, the consent of the research subjects should be acquired when the original consent no longer covers the new research methods with regard to e.g. linking data with data from different registers.

When reading the act it should also be kept in mind that it was prepared in the mid-1990s and approved in 1998, when the means of identifying persons electronically were virtually non-existent and vastly more limited than today. Today, the inadvertent leakage of a person's social security number may pave the way to full disclosure of that person's medical and credit history, not to mention the risk of identity theft. This underlines the necessity of interpreting the law in light of the constitutional right to privacy. In practice, this means that research should primarily be carried out either based on the consent of the data subjects or without personal data whenever possible. When the research calls for linking of the data to other data, this should be carried out in a secure manner by parties other than the ultimate users of the data, i.e. the researchers.

In most cases, personal data in public registers is regarded as secret under the Finnish FoIA. The same applies to personal data that has voluntarily been given to an authority for research or statistical purposes.[14] Most registers are subject to specific legislation that also determines the terms of handing over personal data from that registry. As a general rule, an authority may grant access to a secret document for research purposes unless otherwise prohibited by law, presupposing that access will clearly not violate the interests protected by the secrecy provision. When considering whether to grant permission to hand over the information, the authority should also take into account the safeguarding of the freedom of scientific research. (Section 28, FoIA)

In other words, at last instance, it is up to the public authority to decide whether the conditions for handing over secret personal data are fulfilled in each individual case. When determining whether secret personal data may be handed over for research purposes, the public authority must take into account both judicial and expediency considerations. The judicial consideration refers primarily to ascertaining that all the prerequisites for processing personal data for research purposes under the Personal Data Protection Act are satisfied. (Section 14, PDA; see above)[15] In addition, when giving consideration to expediency, the authority should ensure that the processing of personal data is not likely to infringe upon the interests that the secrecy provisions are supposed to protect.[16] It should be noted that the data subject is not given a specific right to prohibit the handing over of her personal data. Whether, in an individual case, such right could be regarded as arising from the constitutional protection of the right to the protection of private life, is open to interpretation.

The informational self-determination of citizens has been safeguarded in cases where information is collected from individuals on a voluntary basis or otherwise subject to contract. In such cases, the information may be handed over only subject to the conditions for use and access laid down in the original consent. (Section 28, FoIA)

If the permission to receive the information is sought from several public bodies under a single ministry, the permission will be sought from and granted by the ministry. With regard to registers in the area of health and social welfare, the relevant authority is the Ministry of Social and Health Affairs.

Permission for gaining information from secret documents may be granted for a limited time period and must be accompanied by necessary stipulations for protecting public and private interests. The authority can also withdraw the permission when necessary.

13 Cf. Government Proposal 96/98.

14 For a list of secret official documents, cf. Section 24 of the Finnish FoIA.

15 Cf. the Government proposal for the Act on the Openness of Government Activities (HE 31/98).

16 Cf. Government Proposal 96/98.

2. Biobanks under Finnish law

The Biobank Act (688/2012) was approved by the Parliament in autumn 2012 and entered into force in September 2013. The basic principle adopted in the law is that the inclusion of samples and their further use is covered by the prior informed consent of the donor. The consent can cover all biobank research. (Section 11, Biobank Act) The consent must specifically include permission to add complementary information, for example of the donor's disease history, to enable the biobank to combine this type of sensitive information with the donor's personal data. (Section 14, Biobank Act)[17]

The biobank may hand over necessary personal data to be combined with data in registers at the Institute of Health and Welfare if combining the data can be justified in relation to the aims of the research project and the release of the data satisfies the terms and conditions of the law in other respects. Personal data can only be handed over for combination with register data if it is coded for the specific project, unless the data subject has given separate consent for the handing over of identifiable personal data. (Section 28, Biobank Act)

3. National Institute for Health and Welfare (THL)

The National Institute for Health and Welfare (THL) hosts statistical and register data on social welfare and health care, diseases and treatments. It grants permission to use register data for scientific research according to the following procedures. With regard to national health registers (cancer registry, implant register, etc.), THL grants permission for use but must acquire the opinion of the Finnish Data Ombudsman. If the research proposal requires linking the data to other data, identifiers can be included in the data.

With regard to community level patient records or social welfare records, THL itself grants permission to use identifiable data, usually in a few weeks' time. With regard to in-house research using its own registries, THL only grants permission following an ethical evaluation. Data may be combined with data from other sources, including Nordic databases, provided that this is specified in the original application for the data.

4. Social Insurance Institution of Finland (KELA)

The Social Insurance Institution of Finland (KELA) hosts a number of registers relating to national health insurance, of which the most important ones are the medicines reimbursement statistics and the national prescription drugs register. KELA may hand over personal data for research purposes when this is regarded as fulfilling the prerequisites set in out in Section 28 of the Finnish FoIA. The data are usually de-identified or the consent of the data subject is given for release of data to be linked to other personal data. With regard to health-related research, KELA usually grants permission following an ethical evaluation by its ethics committee. Permission from the Institute of Health and Welfare is also needed in such cases.

5. Ministry of Social and Health Affairs

The Ministry of Social and Health Affairs grants permission to researchers who are applying for use of register data from two or more institutions under its sphere of administration, e.g. Finnish Medicines Agency.

When register data is used for scientific research, the data controller normally notifies the Data Ombudsman unless there is a legal exemption from this notification.

17 Opinion of the Constitutional Law Committee 10/2012.

6. Statistics Finland

Statistics Finland can hand over secret data for the purposes of scientific research. (Section 13, Statistics Act (361/2013)) Under the law, Statistics Finland may grant permission to use its basic data at its own discretion. According to the recent amendment of the Statistics Act, Statistics Finland can grant access to de-identified data, i.e. data stripped of direct identifiers, for research purposes. Complete anonymisation of data for research purposes is no longer required.[18] In practice, this means that access to de-identified data for research purposes is granted only via Statistics Finland's closed online system. Only anonymised datasets are handed over to researchers outside the online system.

Statistics Finland currently grants access to statistical microdata in the following ways:

1. Via its online service, in which case access to de-identified data or identifiable data may also be granted. The research output will be controlled before publication.
2. In its research laboratory.
3. By releasing anonymised sample datasets for research use. If a researcher wishes to combine the statistics data with other data, this must be done at and by Statistics Finland.

In practice, Statistics Finland does not grant access to population-based registers as such but only to samples from the registers. The data are distributed either via Statistics Finland's online service or disseminated as anonymised microdata on CDs or DVDs.

If a researcher is entitled to process identifiable data under the data protection law and if the research will not be possible without this data, data relating to age, sex, education and occupation may be included in the datasets. (Section 19, Statistics Act) Identifiable data may also be delivered to other statistics authorities belonging to the European Statistical System for the development of European statistics. (Section 13.2(3), Statistics Act)

With regard to handing over data to Nordic statistics agencies for the purpose of linking data for subsequent use in scientific research in compliance with the rules of that country, it appears that this provision may be interpreted to permit delivery of data with identification codes to other statistics agencies that are entitled to handle identifiable data under their own national data protection law. This can hardly be regarded as compromising the right to privacy of the data subjects. At the same time, it will help to raise the level of scientific research by making it possible to carry out research that could otherwise not be carried out. The free movement of personal data has been harmonised in the EU under Directive 95/46/EC, which sets out the framework for cross-border delivery of personal data within the EU. Moreover, after the proposal for the General Data Protection Regulation has been approved, data protection legislation will be identical throughout the EU and the rights of data subjects will be safeguarded on an equal basis, regardless of where the data are being processed.

A separate act allowing data to be handed over with identifiers for research purposes governs the use of data on the cause of death.

7. Population Register Centre of Finland

The Population Register Centre of Finland will hand over data with identifiers for research purposes if it is necessary to link the data to data in other registers and the applicant can demonstrate that the data will be secure. The handing over of data is permitted under the Act on the Population Register Centre (61/2009) and is governed by the Personal Data Protection Act. Data may also be hand over to researchers who do not reside in Finland, but they must have some sort of institutional contact with a Finnish research institution.

18 The Bill for amending the Statistics Act HE 154/2012.

8. Ethical evaluation of research projects in Finland

In Finland ethical evaluation is mandatory only under the act on medical research (488/1999, as amended by act 794/2010). The evaluation is conducted by the ethics committee of the hospital district in which the director or Principal Investigator, i.e. the person in charge of the research project, is located. For clinical studies, the ethical evaluation is conducted by the National Committee on Medical Research Ethics.

Otherwise, research institutions and register-hosting bodies have their own voluntary ethical review process.

9. Granting access to register-based microdata to researchers from other EU countries

All Finnish organisations hosting public register data grant access to foreign researchers under the same conditions that apply to Finnish researchers. This does not, however, apply to researchers residing outside of Finland who wish to obtain access to statistical microdata via the online system at Statistics Finland.

Sweden

1. General legal framework

Access to statistical microdata in Sweden is governed by the Public Access to Information and Secrecy Act (Offentlighets- och sekretesslagen, 2009:400), the Personal Data Act (1998:2004) and the Ethical Review Act (2003:460). There are various other specific laws, such as the Act on official statistics (SFS 2001:99), act on health data registers (SFS 1998:543), Act on forensic psychiatry research registers (SFS 1999:353), Ordinance on medicinal side-effect registers (SFS 1997:143) and ordinance on medical service registers under the National Board of Health and Welfare (SFS 1993:1058) that are relevant for use of register data in their respective fields of application. The Archives Act (SFS 1990:782) and the Archives Decree (SFS 1991:446) are of relevance to archiving of research.

In principle, the legislative framework in Sweden is the same as in Finland but there are certain differences. The biggest difference is that all processing of sensitive data for research purposes, as well as research involving other sensitive personal data (e.g. on criminal offences) or that constitutes a physical or psychological interference with patients or relates to biological material which is traceable to identifiable persons, is subject to a statutory ethical review process. (Sections 3 and 4, Ethical Review Act)

According to the Personal Data Act, sensitive personal data may be processed for research and statistics purposes, provided that the processing is defined as necessary under the law and that the interest to society of the research or statistics project under which the processing will take place is manifestly greater than the risk of violation of the personal integrity of the individual(s) involved. (Section 19, Personal Data Act) If such processing has been approved by a research ethics committee, the prerequisites of the law are deemed to be satisfied. In practice, this means that all research involving processing of sensitive personal data is subject to ethical review. 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. In addition, the registry-hosting authority has the obligation to determine whether there is a basis for handing over data for research purposes in each individual case.

In the ethical review legislation, the term “research” is defined as scientifically experimental or theoretical work to obtain new knowledge or applied research carried out on scientific grounds. Research carried out in higher education at the university level for basic or advanced degrees is not considered

scientific research. According to the instructions of the Central Ethical Review Board, non-experimental observational research and other non-interventional research that is carried out via surveys or interviews is also to be regarded as research, and is thus subject to statutory ethical review.[19]

The Ethical Review Act applies to research conducted in Sweden.

2. Granting access to statistical microdata in Sweden

According to the Statistics Act (SFS 2001:99), data contained in official statistics must not be matched with other data for the purpose of ascertaining the identity of an individual. (Section 6) However, in connection with the disclosure of data relating to an individual who is not directly identifiable, a statistics agency may attach a reference number to the data so that it can be linked by the agency to a personal identification number or equivalent, thereby making it possible to supplement the data at a later date, for example for the purposes of research or statistics. (Section 16.1) This provision explicitly permits the carrying out of longitudinal studies and, if justified by the aims of the research in question, the linking of data from other registries.

Sweden has an online system at Statistics Sweden, Microdata Online Access (MONA), offering researchers access to de-identified statistical data. All applications must be approved by Statistics Sweden on the basis of two issues: whether the application refers to research in the meaning of the Swedish law and whether there is a risk of infringement of the integrity of the data subjects. Data requests relating to access to sensitive data require a prior ethical review. It is, however, possible to receive complementary data from Statistics Sweden outside the MONA system, when required for a research project.[20]

3. Access to microdata at the National Board of Health and Welfare and other registry-hosting organisations

Statistics Sweden does not store all national register data, and data must also be sought from other organisations. This precludes remote access to applications that do not store data at Statistics Sweden. The most important data source outside Statistics Sweden is the National Board of Health and Welfare. Register data can be obtained for research purposes in a de-identified form from the board following an ethical review and subsequent harm test by the board. If data must be matched with researchers' own data, the researchers can bring the data to the National Board of Health and Welfare, which will match the datasets. If the research project requires the matching of data from various organisations, the application is sent to all the organisations, and the organisations will decide among themselves the best way to match the data. In exceptional circumstances personal data could be handed over to the researcher in identifiable but encrypted form.

4. Biobanks under Swedish law

In Sweden, biobanks are currently regulated under the Biobanks in Medical Care Act (297/2002). This law covers biobanks within the health care system and applies only to the storing of tissue samples and processing of data necessary for tracking donors. Other forms of processing of personal data in the biobank are covered by the Personal Data Act.

Establishing a biobank for research purposes or clinical trials requires prior authorisation from the relevant research ethics committee. After that, the biobank may only be used for that specific purpose without further approval from the research ethics committee. (Chapter 2, Section3, Biobanks in Medical Care Act)

19 Cf. Angående ändringar i lagen (2003:460) om etikprövning av forskning som avser människor (etikprövningslagen) m.m., Central etikprovningsnåmnden, 26.5.2008.

20 Registerdata för forskning, delbetänkande från Fi 2011:05 Statistikutredningen 2012, Direktiv 2012:15, p. 38.

Under the present law, the use of biobank samples for research purposes requires the permission of the data subject. Consent is also required 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. (Chapter 4, Section 5)

However, in cases where already existing tissue samples are used for research purposes or for clinical trials, the research ethics committee that approves the new purpose for the biobank will also determine the requirements relating to the information and consent regulations that will be applied. (Chapter 3, Section 5)

The released tissue samples must be deidentified or coded, unless otherwise decided. Code keys are to be kept on the premises of the care provider and stored securely. (Chapter 3, Section 4) If the 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 cannot be connected with the tissue sample (Chapter 3, Section 10)

A proposal for a new biobank law was published in 2010. This proposal introduces the right to informational self-determination for data subjects, which means that the proposed Swedish Biobank Register and other biobank registers couldn't process personal data against the wishes of the donor except in cases when tissue samples could be stored regardless of the donor's position, for example in communicable disease control and compulsory mental care.[21] The proposal has not yet led into new legislation.

5. Granting access to register-based microdata to researchers from other EU countries

In principle, Statistics Sweden may grant access to statistical microdata to researchers from other EU countries. Applications from other EU countries are assessed on a case-by-case basis. Given that accessing identifiable information is subject to both the data protection act and the publicity and secrecy act, access to identifiable personal data is not granted outside Sweden as it is regarded as beyond the scope of application of Swedish secrecy legislation.

Norway

1. General legal framework

Just like the other Nordic countries, Norway has incorporated the data protection directive of 1995 into its data protection legislation (the Act relating to the processing of personal data (14/2000)). As in the other Nordic countries, the processing of personal data for research purposes can be carried out to perform a task in the public interest (Section 8(d)). Sensitive personal data may only be processed if the processing is necessary for historical, statistical or scientific purposes, and the public interest of the processing clearly exceeds the disadvantages it may entail for the natural person. (Section 9.1(h))

There is special statutory regulation with regard to data protection issues in medical research, primarily under the Act on personal health data filing systems and the processing of personal health data (24/2001), hereafter referred to as the Personal Health Data Filing System Act. The purpose of the Act is:

> *[t]hrough research and statistics [...] to contribute towards information on and knowledge of the state of public health, causes of impaired health and illness trends for administration, quality assurance, planning and management purposes. The Act shall ensure that personal health data are processed in accordance with fundamental respect for the right to privacy, including the need to protect personal integrity and respect for private life and ensure that personal health data are of adequate quality. (Section 1)*

21 En ny Biobankslag, SOU 2010:81.

2. Biobanks under Norwegian law

Biobanks for research purposes are regulated under the Act on medical and health research (44/2008, the Health Research Act). A research biobank is defined as a collection of human biological material that is used in a research project or that is going to be used for research. (Section 4(c)) The Act applies to all medical and health research on human beings, human biological material or personal health data. (Section 2) Establishing a research biobank requires approval by a Regional Committee for Medical and Health Research Ethics. (Section 25)

Consent must be obtained from participants in medical and health research, unless otherwise laid down in law. Consent must be informed, voluntary, express and documented. Consent must be based on specific information about a concrete research project, unless there is a case for granting broad consent. (Section 13) Broad consent can cover the use of human biological material and personal health data for specific, broadly defined research purposes. The Regional Committee for Medical and Health Research Ethics may specify conditions for use of broad consent and may require the project manager to obtain new consent if the committee deems it necessary. Participants who have given broad consent are entitled to receive information about the project at regular intervals. (Section 14)

The documentation, storage and use of data in a research biobank require the voluntary, express and informed consent of the data subject and, in the case of biological materials, the donor of the tissue samples. The material in such a biobank may not be lent or disclosed to others or transferred to another country unless this follows from the consent given.

If previously collected material and data are to be put to different, wider or new use that does not lie within the scope of the original consent, new voluntary, express and informed consent is required. If it is difficult to obtain new consent, the Regional Committee for Medical and Health Research Ethics may approve the new or changed use of previously collected human biological material or personal health data without new consent being obtained. This may only be applied if the research in question is of significant interest to society and the participants' welfare and integrity are ensured. (Section 15)

3. Granting access to data at Statistics Norway

Statistics Norway grants access to data to researchers at approved research institutions in Norway and to students pursuing a Master's or PhD degree in Norway. Individual post-graduate researchers may be granted access to de-identified data when the research is conducted under the supervision of a qualified employee at an approved research institution.

Statistics Norway supplies only anonymised or de-identified data. If the data include sensitive data, a prior recommendation for the use of the data is needed from the Ombudsman for Privacy in Research or permission must be sought from the Norwegian Data Protection Authority. The researcher is responsible for reporting to the Ombudsman or the Data Protection Authority even if their recommendation/permission is not required. The Norwegian Social Science Data Services serves as the Ombudsman for Privacy in Research on behalf of the majority of Norwegian research institutions.

Permission from the Regional Committee for Medical and Health Research Ethics is required for health research projects. Health research projects are defined as projects using scientific methods to obtain new knowledge within the field of health and illness. For other projects, decisions regarding exemption from confidentiality provisions are taken by the individual organisations hosting the registries.[22]

Statistics Norway does not normally grant access to data for use outside Norway. In cases where access to data can take place through a country's national statistics agency, Statistics Norway may supply de-identified individual data to researchers abroad. The local agency must also have confidentiality

22 For a table of Norwegian data sources and exceptions from confidentiality, see: http://www.ssb.no/omssb/tjenester-og-verktoy/data-til-forskning

provisions corresponding to those in Norway. In practice, it appears that researchers in other Nordic countries could gain access to Statistics Norway's de-identified microdata if access is organised by their own statistics authority.

Completely anonymous individual data can be supplied to a researcher abroad, provided that the recipient meets the general requirements set out by Statistics Norway for the provision of statistics for research in Norway. If the data are linked to other data, consent from the primary registry owner may be necessary even if the data are linked to anonymous data. The Data Protection Act, however, does not apply when the data are anonymous.

In 2011 Statistics Norway and the Norwegian Social Science Data Archive were awarded a grant to develop the Remote Access Infrastructure for Register Data (RAIRD). The purpose of the infrastructure is to support social science research using statistical microdata, but the use of microdata in other fields utilising register data is also envisaged.[23]

4. Access to data stored at the Norwegian Institute of Public Health

According to the guidelines for delivery of data from central personal health data registers, no permission is required for:

- access to statistical data (tables), or
- access to anonymous data from one central personal health data filing system, or
- linking data from two or more such registers, also when it involves accessing de-identified data.[24]

Permission from the Data Protection Authority or a Regional Committee for Medical and Health Research Ethics is required for use of personal identifiable data. The use of data in medical or health research projects requires the approval of a Regional Committee for Medical and Health Research Ethics.

Access to data from the Norwegian Prescription Database, either separately or as linked data, always requires the approval of a Regional Committee for Medical and Health Research Ethics. The Norwegian Data Protection Authority must also be informed.

Data from one of the central personal health data registers may be released to projects for a purpose other than medical or health research. Access to data is granted in accordance with the individual registry's regulations. The data manager in charge of the dataset is liable for the use of the dataset in accordance with the regulations.[25]

CONCLUDING REMARKS ON THE CURRENT NORDIC SITUATION WITH REGARD TO SHARING REGISTER-BASED RESEARCH DATA

The purpose of this report has been to present an overall picture of the legal framework for using register–based microdata across the borders of the Nordic countries. When looking at the Nordic legislation relating to register-based research from this point of view, it appears that any actual obstacles to combining data from different registers in one country and across borders lie not so much in the legal framework as such, but rather in the current practices and uncertainties in applying the law.

23 Cf. Information on the Research Council of Norway website, available at: http://www.forskningsradet.no/prognett-infrastruktur/Nyheter/Easier_access_to_Norways_registry_data/1253970519527/p1224697900506.

24 Guidelines for delivery of data from central personal health data filing systems, available at: http://www.fhi.no/dav/4db1cb039e.pdf.

25 Ibid.

When personal data included in public registers is available for reuse for research purposes pursuant to the national freedom of information legislation and subject to applicable data protection law and any registry-specific law, such reuse should also be possible in a cross-border setting within the EU. The recently amended Directive 2013/37/EU on the reuse of public sector information provides the general framework for the reuse of public sector information that is available for reuse under national freedom of information legislation. If the information contains personal data, reuse is subject to applicable national data protection law.[26] Harmonised European data protection law will provide a basis for cross–border research projects using register-based personal data at the general level. The eventual harmonisation of data protection legislation by EU regulation will hopefully remove the remaining differences in national implementation of the data protection rules with regard to use of data in research.

Currently, the greatest uncertainty regarding cross-border use of register–based microdata lies in the practices of the national statistics authorities. Given that the laws governing secrecy provisions in the national freedom of information legislation relating to information produced by the public sector have not been subject to full harmonisation in the EU, it is not necessarily possible to grant access to statistical microdata to individual researchers abroad. However, if the data are delivered to another statistics agency that creates the necessary links and combines them with other data and subsequently anonymises or pseudonymises the datasets before delivering them to researchers, this should not jeopardise the privacy of the data subjects.

Under the Finnish Statistics Act, data stored at Statistics Finland may be delivered abroad with certain identification information if the recipient of the data is entitled to process the data under local law. In practice, Statistics Finland does not, however, deliver any data with identification information abroad. Data stored in the registries hosted by the Finnish Institute of Health and Social Welfare may be delivered to researchers from other EU countries if the research application satisfies the requirements of the data protection law. Usually the data are delivered in a coded form, but can be delivered with identification numbers as well, if this is necessary for carrying out the research in question.

Statistics Norway may deliver de-identified microdata abroad when access to the data takes place at the local statistics agency. This means that researchers in other Nordic countries could gain access to Statistics Norway's de-identified microdata if access is organised by their own statistics authority. Completely anonymous individual data can be supplied to a researcher abroad, provided that the recipient meets the general requirements set out by Statistics Norway for the provision of statistics for research in Norway. If the data are linked to other data, consent from the primary register owner may be necessary even if the data are linked to anonymous data.

Statistics Sweden may grant access to its microdata to other EU countries. However, this applies only to anonymous data, because granting access to identifiable personal data outside of Sweden is regarded as an infringement of Swedish secrecy legislation.

It is not possible to gain access to Statistics Denmark's microdata from abroad via the agency's online system; however, Statistics Denmark will combine data with outside datasets. Statens Serum Institut can combine data from Statistics Denmark with biobank data.

With the eventual harmonisation of European data protection legislation through EU regulation, handing over of personal data for research purposes will be governed by this regulation. Personal data may be handed over under the conditions set out in the regulation for that particular type of data and may be subject to any applicable national law permitted by the regulation.

The mutual recognition of research permissions granted by the ethical review mechanisms in the Nordic countries should be achievable in order to reduce bureaucracy in Nordic research projects. With regard to interventional medical research, an ethical review is statutory in all the Nordic countries, and some adjustment of practices may be required to achieve reciprocal recognition for the purpose of cross-border research. With regard to social science research, ethical review is only statutory in Sweden and it should be further investigated whether changes in the Swedish law would be required in this respect.

26 For more detail, see Opinion of the Article 29 Working Party, Opinion 06/2013 on open data and public sector information (PSI) reuse, 5 June 2013.

Annex 3
Status of the revision of the EU data protection framework

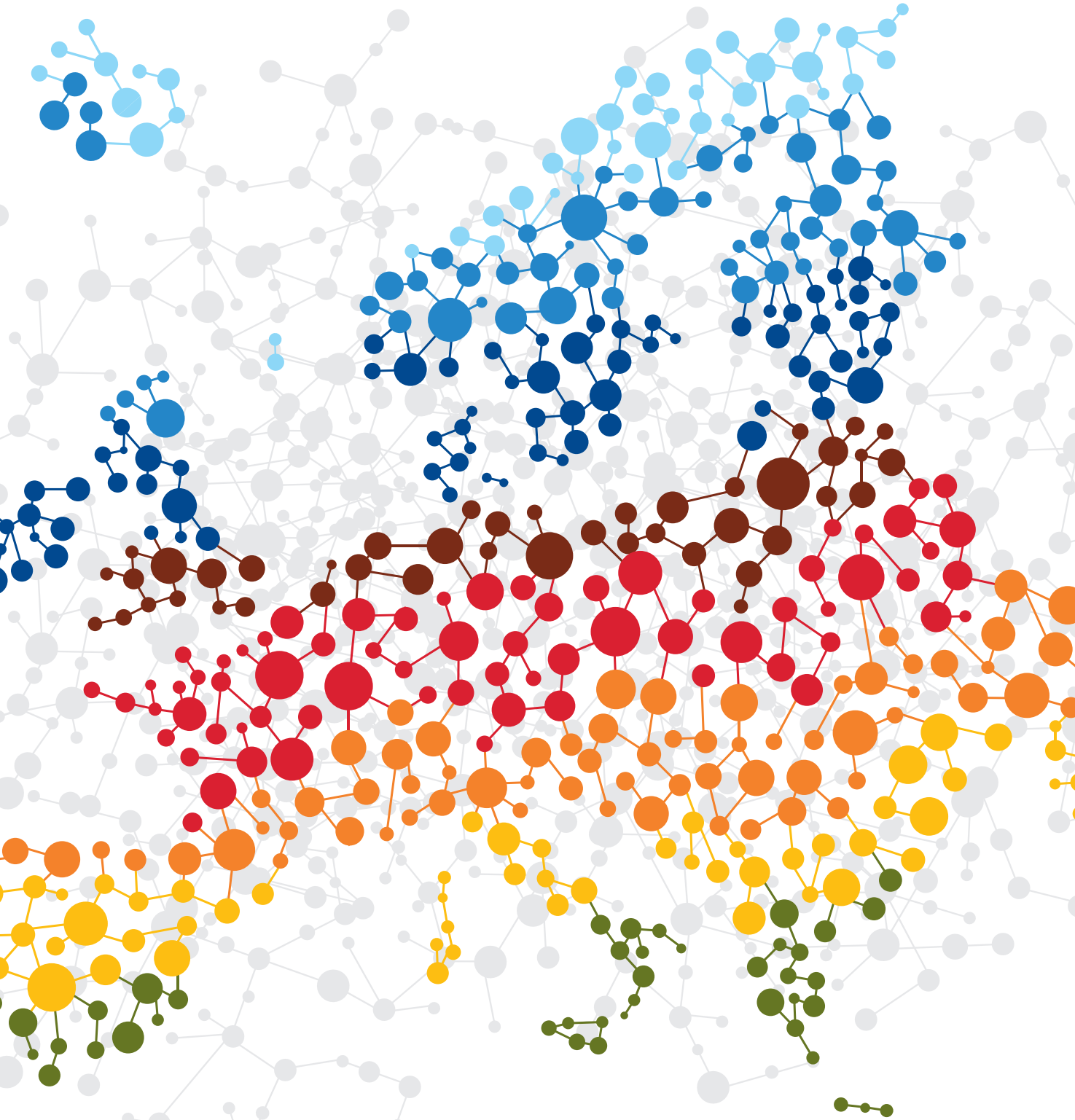

Illustration: Shutterstock/shoaarts

Annex 3
Status of the revision of the EU data protection framework

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THE SLOWLY EMERGING EU DATA PROTECTION FRAMEWORK

Impact on scientific research[27]

Introduction

In January 2012 the European Commission published a legislative package to reform the European data protection legislation. The proposed reform is based on the principles of protecting personal data as a fundamental right of citizens, while at the same time securing the free flow of personal data within the Community as a common good. The data protection package consists of two sets of rules: the first is the General Data Protection Regulation (hereafter the Regulation)[28] and the second is the directive that deals with cross-border crime prevention and other policing matters[29]. Once it has been approved, the proposed legislative package will entail the complete harmonisation of general data protection legislation in all Member States, and the General Data Protection Regulation will be directly applicable law throughout the EU. The scope of national implementations will be explicitly defined in the Regulation.

The following provides a general overview of the impact of the Regulation on scientific research. Due to the frequent issuing of new versions of the Regulation from different institutional bodies, this article will be limited to discussing the Commission's original proposal and the amended version of the Regulation approved by the European Parliament, hereafter the Parliament Resolution.[30]

A3.1. Legal basis: data protection as a fundamental right of the European Union

The right to data protection is introduced as a fundamental right and a distinct right from the right to privacy in the Charter of the Fundamental Rights of the European Communities (2000/C 364/01). According to Article 8 of the Charter, everyone has the right to the protection of personal data concerning him- or herself. It is further provided for in the Charter that 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.

27 This article was commissioned by NordForsk as a background study for the NORIA-net Registers and Biobanks working group.

28 Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) COM/2012/011 final.

29 Proposal for a Directive of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and the free movement of such data. 25 January 2012. COM(2012) 10.

30 Protection of individuals with regard to the processing of personal data, European Parliament legislative resolution of 12 March 2014 on the Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) COM(2012)0011 – C7-0025/2012 – 2012/0011(COD)

Moreover, the fundamental right to the protection of personal data as part of the general right of privacy is set out in Article 8 of the European Convention on Human Rights, which also sets the limitations to this right. Limitations permitted in respect of right to privacy must be in accordance with the law and necessary in the interests of a democratic society. As enumerated in the Convention, such interests include national security, public safety or the economic wellbeing of the country, the prevention of disorder or crime, the protection of health or morals, and the protection of the rights and freedoms of others.

It must also be pointed out that the EU Charter is the first instance in which a distinction is made between the right to privacy on the one hand and the right to the protection of personal data on the other. From a societal point of view, these two rights serve different purposes: the right to privacy protects the opacity of personal information primarily against government intervention, whereas the right to data protection focuses on the transparency of the processing of data. In general, the principles of data protection must be followed irrespective of whether the processing is done by public or private entities. [31]

Both the Charter and the European Convention of Human Rights are based on the principle that individual rights are not absolute but must be balanced against each other. With respect to the right to data protection, and depending on the case in question, other relevant basic rights include the right to the integrity of the person, freedom of information and the right to conduct business as well as intellectual property rights.

A3.2. Scope of application of the Regulation

A3.2.1. Purpose of the Regulation

The current European data protection framework has been instituted through the Data Protection Directive of 1995 (Directive 95/46/EC).[32] Given the time passed since the drafting of the directive, and in particular the new technological environment that has evolved during the past two decennia, it is obvious that certain aspects of the directive need to be amended to serve their original purpose, also in the environments where personal data is being processed for various purposes in the public and private sectors. Moreover, the years have shown that the directive has not been successful in harmonising the legislation in Member States with regard to protecting citizens in relation to the processing of their personal data on the one hand, and securing the free movement of such data within the Community on the other. However, it is also clear that because the legal basis of data protection rests on the fundamental right to privacy and to data protection, the material scope of the new EU data protection framework should be the same as the current framework.[33]

In January 2012 the Commission proposed a new set of rules for protecting personal information and regulating the free movement of personal data within the Community. The proposed reform of data protection legislation is based on the principles of protecting personal data as a fundamental right of citizens while at the same time securing the free flow of personal data within the Community as a common good. The data protection package consists of two sets of rules: the first is the General Data Protection Regulation (hereafter the Regulation)[34] and the second is the directive that deals with cross-border crime prevention and other policing matters[35].

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31 For further details, please see: Kokott, J.,& Sobotta, C., The distinction between privacy and data protection in the jurisprudence of the CJEU and the ECtHR, International Data Privacy Law (2013), doi: 10.1093/idpl/ipt017, and Fuster, G., & Gutwirth, S., Opening up personal data protection: a conceptual controversy, Computer Law & Security Review 29 (2013), 531-539.

32 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

33 Report on the proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (COM(2012)0011 – C7-0025/2012 – 2012/0011(COD), Report of Jan Philipp Albrecht for the EU Parliament's Committee on Civil Liberties, Justice and Home Affairs (LIBE), hereafter the Parliament Resolution, available at: http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2014-0212

34 Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) COM/2012/011 final.

35 Proposal for a Directive of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and the free movement of such data. 25.01.2012. COM(2012) 10.

The general purpose of the Regulation is on the one hand to protect individuals with regard to the processing of personal data and on the other hand to guarantee the free flow of personal data between the Member States. Since achieving these to a certain extent contradictory aims was not successful under the current directive, the Commission now aims to institute an equal level of protection of the rights and freedoms of individuals with regard to the processing of personal data in all Member States. (Recital 8)

In this regard, the Commission derives its mandate for issuing a Regulation from Article 16(2) of Treaty on the Functioning of the European Union, according to which the European Parliament and the Council shall lay down the rules relating to the protection of individuals with regard to the processing of personal data by Member States when carrying out activities that fall within the scope of Union law and the rules relating to the free movement of such data.

A3.2.2 Defining personal data

The Regulation applies to the processing of personal data. Thus the way in which this type of data is defined is crucial for the application of the Regulation. Also, with the evolution of technologies, the concept of personal data has changed considerably, particularly in the digital communication environment. The possibility of combining data from various sources across the Internet makes the risk of identifying a particular person much greater than in the analogue world. In order to harmonise the current divergent national implementations of the data protection directive, what is considered as personal data is subject to explicit definition in the Regulation.

Given that the purpose of data protection is to protect the personal data of the data subject, defining the data subject constitutes the basis for determining what is to be regarded as protectable personal data. According to Article 4 of the Regulation, "personal data" means any information relating to an identified or identifiable natural person, later referred as the "data subject". An identifiable person is further defined as *one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, unique identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social or gender identity of that person.* (Article 4, Paragraph 2, Parliament Resolution)

If identification requires a disproportionate amount of time, effort or material resources, the natural living person shall not be considered identifiable. When determining whether a person is identifiable, account should be taken of all the means reasonably likely to be used either by the controller or by any other person to identify or single out the individual directly or indirectly. To ascertain whether means are reasonably likely to be used to identify the individual, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration both available technology at the time of the processing and technological development. (Recital 23, Parliament Resolution)

Anonymised data

Data protection principles are not applied to anonymised data. In the Parliament Resolution, **anonymised data** is defined as information that does not relate to an identified or identifiable natural person. (Recital 23, Parliament Resolution). This means that the processing of anonymised data for research and statistical purposes does not fall within the scope of application of the Regulation. (Ibid.) **The Regulation does, however, apply to processing in which identifiers can be linked to an identified or identifiable natural person.** Such identifiers include IP addresses, cookies and radio frequency tags and other devices, applications, tools and protocols that can be linked to a natural identifiable living person. (Recital 24, Parliament Resolution)

Pseudonymised data

Personal data that cannot be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organisational measures to ensure non-attribution, is referred to as **pseudonymous data**. (Article 4, Paragraph

2.a, Parliament Resolution) This definition follows the interpretation of the concept of personal data by the Article 29 Working Party, according to which pseudonymous data is to be considered information about persons who are indirectly identifiable if the possibility of retracing the pseudonyms back to the data subject remains.[36]

The Commission's original proposal did not contain a definition of pseudonymous data, but the different versions that have been drafted since by different institutions have inserted this term, albeit differently defined. The definition of pseudonymous data is important to the extent that processing personal data in a pseudonymous form in certain cases is possible with fewer restrictions from the controller's point of view. However, what is certain is that processing of pseudonymous data lies firmly within the scope of application of the Regulation.

Moreover, the Parliament Resolution has added a separate definition for **encrypted data**, which is defined as personal data that through technological protection measures is rendered unintelligible to any person who is not authorised to access it. (Article 4, Paragraph 2.b, Parliament Resolution) Thus, encrypted data is considered a type of pseudonymous data that is protected by strong technological algorithms.

The intention of the Commission was for the new Regulation to be technologically neutral. (Recital 13) Because of the broad definition of personal data used, including, i.a., IP addresses, genetic data and geo-location data, it will be necessary to define the requirements for rendering data anonymous for data protection purposes. An internal study conducted by the Commission proposes that the conditions for successful anonymisation are introduced into the articles of the Regulation. According to the study, those conditions should include:

1. requirements for anonymisation itself, and
2. requirements for the processing of anonymised data.[37]

In the proposed Regulation, data processors are given wide room to manoeuvre in cases when the processed personal data is pseudonymised. This is the case, for example, when personal data is processed for scientific research purposes. This has caused much confusion in the discussions relating to the Regulation, because in some Member States encoded or pseudonymised data is considered to be identifiable – and thus personal – data in relation to the actors who have the means (the "key") for re-identifying the data, but not in relation to other persons or entities (e.g. Austria, Germany, Greece, Ireland, Luxembourg, the Netherlands, Portugal, the UK). In other Member States, all data that can be linked to an individual is regarded as personal. This is the case also when data are processed by someone who does not have the means for re-identification (e.g. Denmark, Finland, France, Italy, Spain, Sweden). So, for example, **in Denmark, Sweden and Finland pseudonymised register data containing sensitive health information is considered to be personal data to which the data protection act applies, regardless of who holds the key to such information**.

A3.3. Basic principles relating to data processing

A3.3.1 General

The basic principles relating to data protection follow the lines of the existing directive 95/46/EC, clarifying and adding to the issues that have produced difficulties and divergent approaches in implementation. Furthermore, the impact of new technologies on data processing has been taken into consideration. In the following, the main principles of data protection are discussed in relation to their impact on the processing of data for scientific purposes.

36 Article 29 Working Party, Opinion 4/2007 on the concept of personal data.

37 Reforming the Data Protection Package, Study, Directorate-General for Internal Policies. Policy Department A: Economic and Scientific Policy, 2012, p. 26 (hereafter Data Protection Study).

The Regulation incorporates the principles of lawfulness, fairness and transparency of data processing. This means that personal data must be processed lawfully, fairly and in a transparent manner in relation to the data subject. Furthermore, data must be collected for a specified, explicit and legitimate purpose and not further processed in a manner that is incompatible with those purposes.

In Recital 40 it is provided that secondary use of personal data for historical, statistical or research purposes may be permitted if regarded as compatible with the original purpose of processing the data.[38] In such cases, the general principles of data processing would also apply, as would the specific conditions for processing personal data for historical, statistical and research purposes provided in Article 83 of the Regulation. In practice, this means that when data originally collected for other purposes, such as public registers, are used for research purposes after being either anonymised or pseudonymised (key-coded) according to the requirements set out in Article 83, this use would be permitted without acquiring new consent from the data subjects. Under current national law, this kind of secondary use of data is still subject to the general requirements for data processing, i.e. the principle of data minimisation and destruction when the data are no longer necessary for the specific use, etc.

The processing of personal data must be restricted to *what is adequate, relevant and limited to the minimum necessary in relation to the purposes for which they are processed*. In other words processing of personally identifiable data is permitted only insofar as it is necessary to fulfil the purpose for which it is being processed. From this follows that *the consent of the data subject for the processing cannot be considered as valid after the processing of personal data is no longer necessary for carrying out the purpose for which they were collected*.

The processed data must also be **accurate and updated when necessary**. Inaccurate data must be erased or rectified without delay. The accuracy of the data must be evaluated in relation to the purpose of the processing.

Prohibition of storing personal data with the exception of data archiving for research purposes

According to the principle of storage minimisation, personal data should not be kept in a form that permits identification or singling out of data subjects any longer than necessary for the purposes for which it is being processed. Personal data may be stored for longer periods insofar as the data will be processed for historical, statistical or scientific purposes in accordance with the conditions of Article 83 and if a periodic review is carried out to assess the necessity of continued storage.[39]

A3.3.2 Lawfulness of processing personal data

General rule: the data subject's consent to processing

The proposed Regulation prescribes clear conditions under which the processing of personal data is lawful. For the purposes of scientific research the most important one is consent, which has to be given **for one or more specific purposes**. (Article 6.1(a)) The data subject's consent is defined in the Regulation as *any freely given specific, informed and explicit indication of his or her wishes by which the data subject, either by a statement or by a clear affirmative action, signifies agreement to personal data relating to them being processed for one or more specific purposes*. (Article 4.1(8))

According to the Regulation, the data subject may give his or her consent for one or more specific purposes. When asked how to define the purposes of consent, the Commission referred to Article 8.2 of the Charter of Fundamental Rights of the European Union. The Charter stipulates that personal data must be processed fairly for *specified purposes* (italics added) on the basis of the consent of the interested person. This means that the basis of the consent *must always be a specific purpose*; a general open consent for a wide-ranging purpose would not qualify under the terms of the data protection legislation.

38 This recital has been deleted in the Parliament Resolution.

39 Article 5, Paragraph 1, Point (e); see also Amendment 95 of the Albrecht Report.

Consent alone does not, however, always constitute the necessary basis for processing personal data if the person giving the consent is in a significantly weaker position in relation to the data controller.[40] In particular, this refers to situations where the data subject is a child, but it is also relevant in cases relating to provision of health care. If a patient is under the impression that he or she will be denied treatment if he or she does not give permission for processing his or her personal data, this is clearly a situation of significant imbalance. According to the Article 29 Working Party, reliance on consent should be confined to cases where the individual data subject has genuine freedom of choice and is able to withdraw the consent without detriment.[41] In fact, in virtually all cases where services are based on providing personal information for processing, this constitutes a significant imbalance between the data subject and the controller.

According to the Regulation, data may also be processed for other legitimate purposes prescribed by law. One of those purposes is the processing of data for scientific research under the conditions of Article 83 of the Regulation. This means that **processing personal data for scientific research would be possible based on the consent of the person and under the specific conditions given in the consent, or, with regard to secondary uses of personal data and depending on the type of data, according to Article 83**. (Article 6.2) The original proposal for the Regulation did not make a distinction between processing different types of personal data for research purposes, whereas the Parliament Resolution contains stricter safeguards for processing health data for research purposes than for processing other kinds of personal data for research. (For more detail, see Chapter 4.2.)

A3.3.3 Rights of the data subject

General

One of the main purposes of the Regulation is to strengthen the ability of natural persons to enforce their rights with respect to processing of their personal data in the global digital environment. The Regulation obliges the data controller to establish procedures and mechanisms for exercising the rights of the data subject. According to the Regulation the controller shall have transparent and easily accessible policies with regard to the processing of personal data and for the exercise of data subjects' rights. The controller shall also have transparent and easily accessible policies with regard to the processing of personal data and for the exercise of data subjects' rights. *The controller shall provide any information and any communication relating to the processing of personal data to the data subject in an intelligible form, using clear and plain language, adapted to the data subject, in particular for any information addressed specifically to a child*. The data subject has the right to know whether, and under what circumstances and legal basis, personal data relating to him or her are being processed. (Article 11 and 12) The data subject also has the right to obtain from the controller **the rectification of inaccurate personal data**. In addition, the data subject has the right to complete and supplement incomplete data. (Article 16)

Right to be forgotten and right to erasure

The Regulation introduces a new right for the data subject, namely the right to demand that the controller erases personal data and prohibits further dissemination of such data. This right relates in particular to the data collected when the data subject was a child. The exercise of this, so called right to be forgotten is subject to the conditions laid down in the Regulation. The data subject may ask for the erasure of the data when the data are no longer necessary for the purposes for which they were collected or otherwise processed.

The data subject can also ask for the deletion of the data when withdrawing his or her consent on which the processing has been based or when the storage period for which consent was given has expired, and where there are no other legal grounds for processing the data. (Article 17) Storage of data for research purposes, when it is carried out in compliance with the requirements of Article 83 relating to the processing of data for use in research, may constitute such legal ground.

40 According to the Article 7.4, consent shall not provide a legal basis for the processing where there is a significant imbalance between the position of the data subject and the controller.

41 Article 29 Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), WP 131, 15 February 2007, p. 8.

However, an exception to the right of erasure may be made when retention of personal data is necessary for historical, statistical or scientific purposes. (Recital 53) According to the general rule, the data controller is obliged to carry out the erasure without delay, **except to the extent that the retention of the personal data is necessary for historical, statistical and scientific research purposes in accordance with Article 83.** (Article 17.3 (c))

A3.3.4 Obligations of the data controller

Data protection by design and by default

The controller is obliged to establish appropriate technical and organisational measures and procedures in a manner that enables the processing to meet the requirements of the Regulation and ensures the protection of the rights of the data subject. Furthermore, the controller must implement mechanisms for ensuring that, by default, only the personal data necessary for each specific purpose are processed and especially that data have not been collected or retained beyond the necessary minimum for those purposes, both in terms of the amount of data and storage time. In particular, the mechanisms must ensure that by default personal data are not made accessible to an indefinite number of individuals.

With regard to processing of research data, the addition introduced in the Parliament Resolution is of particular interest: *Data protection by design shall have particular regard to the entire lifecycle management of personal data from collection to processing to deletion, systematically focusing on comprehensive procedural safeguards regarding the accuracy, confidentiality, integrity, physical security and deletion of personal data*. (Article 23.1, Parliament Resolution)

Data security

The controller and the processor shall implement *appropriate technical and organisational measures and procedures to ensure a level of security appropriate to the risks represented by the processing and the nature of the personal data to be protected, having regard to the state of the art and the costs of their implementation*.[42] Following an evaluation of the risks, the controller and the processor shall implement these measures and procedures in order to protect personal data against accidental or unlawful destruction or accidental loss and to prevent any unlawful forms of processing, in particular any unauthorised disclosure, dissemination or access, or alteration of personal data.

Parliament added further protection for processing of sensitive personal data. When processing sensitive personal data, additional security measures must be implemented to ensure situational awareness of risks and the ability to take preventive, corrective and mitigating action in near real-time against vulnerabilities or incidents detected that could pose a risk to the data. (Article 30, Paragraph 1.d, Parliament Resolution)

Data protection impact assessment and prior authorisation and prior consultation

The Regulation obliges the data controller to carry out an assessment of the impact of the envisaged processing operations on the protection of personal data in cases where the processing operations present specific risks to the rights and freedoms of data subjects by virtue of their nature, scope or purposes. In the context of such operations the Regulation mentions, *i.a. information on sex life, health, race and ethnic origin or for the provision of health care, epidemiological researches, or surveys of mental or infectious diseases, where the data are processed for taking measures or decisions regarding specific individuals on a large scale, as well as personal data in large scale filing systems on children, genetic data or biometric data*. (Article 33.2)

A data protection impact assessment must include at minimum a general description of the envis-

42 Article 30, Parliament Resolution.

aged processing operations, an assessment of the risks to the rights and freedoms of data subjects, the measures envisaged to address the risks, safeguards, security measures and mechanisms to ensure the protection of personal data and to demonstrate compliance with the Regulation, taking into account the rights and legitimate interests of data subjects and other persons concerned. (Article 34)

If the data protection impact assessment indicates that processing operations are by virtue of their nature, scope or purposes likely to present a high degree of specific risk, the controller must consult the supervisory authority prior to the processing of personal data in order to ensure the compliance of the intended processing with the Regulation and in particular to mitigate the risks involved for the data subjects. This means that, for example, *in epidemiological research a prior consultation of the supervisory authority may be called for*.

A3.3.5 Transferring personal data to countries outside the EU

Under the current data protection directive, transferring data to third countries outside the EU is subject to specific regulations for the purpose of ensuring that the standard of protection for personal data in those countries is at the same level as in the EU. In the post-Snowden era, these rules have been subject to strict scrutiny, and the basic assumption of the Parliament Resolution is that EU citizens should enjoy the same level of protection with regard to processing of their personal data, including the same recourses to justice, as they would in their home country. The Parliament Resolution provides a detailed set of rules governing transfer of personal data to third countries (Articles 41 to 45). It is up to the Commission to decide whether a third country, or a territory or a processing sector within that third country, or the international organisation in question will ensure an adequate level of protection. The criteria to be taken into consideration by the Commission are stipulated in the Regulation. (Article 41)

The transfer of personal data to a third country is, however, possible even if the Commission does not take an adequacy decision or decides that a particular country, territory or international organisation will not ensure an adequate level of protection. In these cases, the data controller or the processor must put into place **appropriate safeguards in a legally binding instrument for the protection of personal data**. The Regulation provides a list of cases in which such safeguards are called for. (Article 42) The Regulation also provides a mechanism for transferring data to third countries by way of binding corporate rules. (Article 43)

Article 44 provides a list of possible instances for derogating from the general rules for transferring personal data to third countries in the absence of an adequacy decision or appropriate safeguards. Transfer is possible, for example, in cases where the data subject has consented to the proposed transfer after having been informed of the risks of such a transfer due to the absence of an adequacy decision or appropriate safeguards. In the preamble it is also stated that *transfers, which cannot be qualified as frequent or massive, could also be possible for the purposes of the legitimate interests pursued by the controller or the processor, when they have assessed all the circumstances surrounding the data transfer*. Moreover, **for the purposes of processing for historical, statistical and scientific research purposes, the legitimate expectations of society for an increase of knowledge should be taken into consideration**. (Recital 88)[43]

43 By comparison, in the Parliament Resolution it is stated that the interests of society in terms of an increase of knowledge should be taken into consideration when assessing whether a particular transfer is possible for scientific purposes. (Recital 88)

A3.4. Special provisions relating to use of personal data for research purposes

A3.4.1 General provisions relating to use of personal data for research purposes

The Regulation includes an extensive set of specific rules relating to the use of personal data for scientific research purposes. These rules constitute a derogation from the general principles of data protection and permit more extensive use of personal data when the conditions of the main principles for use of personal data for scientific research are complied with. Scientific research is given a broad meaning in the Regulation. *Scientific research includes fundamental research, applied research, and privately funded research*. This means that the derogations from the general data protection principles also apply to research conducted by e.g. pharmaceutical or insurance companies. (Recital 125)

The provisions of the original proposed Regulation relating to scientific use have been rewritten by the Parliament and by different Council presidencies. Since there is still no final text from the Council, in the following, the Commission's version of Article 83 will be discussed first, followed by a discussion of the set of rules provided in the Parliament's legislative resolution to be applied to processing of data for scientific research.

Original proposal

The principles relating to processing of personal data for research purposes are prescribed in the Article 83 of the Regulation. Firstly, personal data can be processed for scientific purposes when there is **the consent of the data subject for one or more specific purposes** as required by the Regulation. (Article 6.1) Moreover, personal data can also be processed for research purposes **without the consent** of the data subject in the following cases:

1. if the data are rendered anonymous; or
2. if the purposes of research cannot be fulfilled by processing anonymous data; and
3. if the data enabling the attribution of information to an identified or identifiable data subject are kept separately from the other information as long as the purposes can be fulfilled in this manner.

What this means in practice is subject to wide interpretation. What is unequivocal is that as soon as the data are rendered anonymous they may be used for research purposes, because the rules relating to data protection no longer apply. According to the European Data Protection Supervisor, it should be made clear in the Regulation that the point of departure for data processing for historical, statistical and scientific research purposes should be that such processing is done using anonymised data. Only in cases where the controller can demonstrate that it is not possible to carry out the research with anonymised data may the data be processed in a pseudonymised form.[44]

When it is not possible to process data in an anonymous form, personal data can be processed for research purposes presupposing that the information permitting identification of data is removed and stored securely in a separate place from the data itself. No further guidance is given as to what this means in practice.

New rules proposed by Parliament

In his report approved by the Committee of Civil Liberties, Justice and Home Affairs and subsequently by Parliament in October 2013, the rapporteur for the Committee, Jan-Philip Albrecht, rewrote the provisions relating to processing of personal data for research purposes, taking into account the criticism of these provisions, particularly from the European Data Protection Supervisor. In his report, *a distinction is made with regard to processing any personal data for research purposes on the one hand and in relation to processing health data for research purposes on the other hand*.

44 Opinion of the European Data Protection Supervisor on the data protection reform package, March 2012, at 302.

In the report, which later became Parliament's final legislative resolution on the data protection package, the general principle of processing personal data for research purposes without consent is that the data should either be anonymous or pseudonymous.[45] **Anonymous data** is defined in the Regulation as amended by the Parliament Resolution as *any data that cannot be related, directly or indirectly, alone or in combination with associated data, to a natural person or where establishing such a relation would require a disproportionate amount of time, expense, and effort, taking into account the state of the art in technology at the time of the processing and the possibilities for development during the period for which the data will be processed*.[46]

The Commission's original proposal did not contain a definition of pseudonymous data. In the Parliament Resolution, a **pseudonym** is defined as *a unique identifier which is specific to one given context and which does not permit the direct identification of a natural person, but allows the singling out of a data subject*. (Article 4(2a)) (For further details, see p. 4.)

A3.4.2 Processing health data for research purposes

Health data is considered to be sensitive data under the current and proposed EU legal framework and is therefore subject to stricter regulation. Health data is defined as *any personal data, which relates to the physical or mental health of an individual, or the provision of health services to the individual*. (Article 4, Point 12, Parliament Resolution)

In principle, processing of health data is prohibited. It may, however, be processed in certain exceptional cases defined by law. According to the proposed Regulation, health data may be processed when it is necessary for health purposes and is subject to the conditions and safeguards referred to in Article 81, as well as when processing is necessary for historical, statistical or scientific research purposes and is subject to the conditions and safeguards referred to in Article 83. (Article 9 Paragraph 1, Points h and i)

In the original proposal for the Regulation, processing of health data for research purposes was subject to the same regulation as processing of any other personal data for research purposes. The Article did not set out special requirements for processing of sensitive data. This was criticised in particular by the European Data Protection Supervisor, who called for additional safeguards for processing of special categories of data, such as health data, for scientific purposes.[47]

According to the Data Protection Supervisor, further processing of data concerning health for research purposes lacks a clear legal basis in the current Directive 95/46/EC. According to him, this issue has only been solved in the current proposal for the Regulation. The Supervisor *further recommends that in order to achieve secure cross-border provision of health services the legislator should harmonise national legislation by giving further direction on the requirement of consent, the determination of responsibilities and security requirements*. According to the Supervisor, there is an imbalance in the current Proposal between the detailed grounds for processing data concerning health on the one hand, and the lack of corresponding assurance as to the protection of data subjects in this area on the other.[48]

This criticism has been taken seriously by Parliament. The rules relating to processing of health data are subject to more detailed regulation in its legislative Resolution. First of all, the Resolution emphasises that when processing of health data is necessary it must be based on *Union law or Member State law which shall provide for suitable, consistent and specific measures to safeguard the data subject's interests and fundamental rights to the extent that these are necessary and proportionate, and of which the effects shall be foreseeable by the data subject*. (Article 81.1, Parliament Resolution)

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45 New Article 83, Paragraph 1: Within the limits of this Regulation, personal data that do not fall under the categories of data covered by Articles 8 and 9 may be processed for historical, statistical or scientific research purposes only if:
(a) these purposes cannot be otherwise fulfilled by processing data which does not permit or no longer permits the identification of the data subject;
(b) data enabling the attribution of information to an identified or identifiabledata subject are kept separately from the other information.

46 Recital 23 as amended by Parliament, Report of the Committee on Civil Liberties, Justice and Home Affairs, 2012/0011(COD), 21 November 2013.

47 Ibid. at 300.

48 Ibid., at 299.

According to the Parliament Resolution, **health data can in principle only be used with the consent of the data subject and such processing shall be subject to the conditions and safeguards relating to processing of personal data for research purposes under Article 83**. (Article 81.2, Parliament Resolution) When the processing of medical data is carried out **exclusively for public health purposes of scientific research, the consent of the data subject may be given for one or more specific and similar research activities. The data subject may withdraw consent at any time.** (Article 81.1b, Parliament Resolution) For the purpose of consenting to participation in scientific research activities in clinical trials, the relevant provisions of Directive 2001/20/EC shall apply. (Article 81.1c, Parliament Resolution) From 2016 onward the new Regulation on clinical trials will be applicable in this respect (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).

Member States are also given the possibility to provide in their national legislation for exceptions to the requirement of consent for **research that serves a high public interest**, if that research cannot possibly be carried out otherwise. In such cases, the data in question must be anonymised. If anonymisation of personal data is not considered possible for the research purposes, **the data must be pseudonymised under the highest technical standards, and all necessary measures must be taken to prevent unwarranted re-identification of the data subjects.** The data subject has the right to object at any time to the processing of the data according to the general principles of the Regulation. (Article 81.2a) It has been left to the Commission and the Member States to define what is meant by high public interest in health research. (Article 81.3, Parliament Resolution)

Disclosing personal data in connection with research findings

The original proposed Regulation permits the disclosure of personal information by bodies conducting historical, statistical or scientific research if the data subject has given his or her consent in accordance with the Regulation (Article 7) or if the publication of personal data is necessary to present research findings or to facilitate research insofar as the interests or the fundamental rights and freedoms of the data subject do not override these interests. This calls for balancing the various fundamental rights, such as the right to personal privacy and data protection of data subjects, against the freedom of speech and significant public interest in disclosing the research data. The data may also be disclosed if the data subject has made the data public herself. (Article 83.2) This article was deleted in the Parliament Resolution.

Processing of personal data by archive services

A completely new provision was added in the Parliament Resolution to ensure that archives functioning in the public interest could continue their work for the benefit of society. According to the new Article 83a, personal data may, once initial processing is completed, be processed by archiving services functioning in the public interest, particularly in order to substantiate individuals' rights or for historical, statistical or scientific research purposes. Archiving is subject to the national freedom of information and archiving statutes and the General Data Protection Regulation. In particular, the provision relating to the consent of the data subject and the data subject's right to object to processing must be adhered to.

A3.4.3 Using personal data from public registers for research purposes under the emerging European data protection law

In the negotiations over the General Data Protection Regulation, many countries have emphasised that national freedom of information legislation should still prevail and be applied together with the data protection law. Hence, a new article was inserted in Parliament's report according to which *personal data in documents held by a public authority or a public body may be disclosed by this authority or body in accordance with Union or Member State legislation regarding public access to official documents, which reconciles the right to the protection of personal data with the principle of public access to official documents*. (Article 80a, Parliament Resolution)

This would mean, for example in Finland, that personal data from public registers could be handed over for research purposes according to Section 16.3 of the Act on the Openness of Government Activities (621/1999) (Finnish Freedom of Information Act (FoIA)) which permits access to personal information from a public register if the person requesting access has the right to record and use such data according to the legislation on protection of personal data, unless otherwise provided in other legislation.

Personal data that is subject to secrecy under the Finnish FoIA and held by a public authority can be handed over for research purposes if this does not infringe upon the rights of protection for which the secrecy provision has been enacted. It is further provided that in individual cases under consideration by the authority, the interests of the freedom of scientific research must also be taken into consideration. However, if the authority has acquired information in the document that is subject to the consent of the person whose interests are protected by the secrecy provision, the permission may only be granted subject to the terms for use and access as stipulated in the consent. (Section 28, FoIA) This means that **personal information that has been acquired for research purposes on the basis of the consent of the data subject may only be used for the purposes given in such consent**.

Thus, handing over of personal data from public registers for research purposes is currently possible under the FoIA if the receiver of the data satisfies the requirements of the personal data processing act in relation to processing of data for research purposes without the consent of the data subject. In addition, the prerequisites for handing over personal data provided in any register-specific legislation must also be satisfied.

For the future, this would mean that handing over of personal data from public registers for research purposes could be possible in Finland, presupposing that the provisions of Article 83 of the proposed Regulation are abided to, i.e. the data is anonymised or pseudonymised, and depending on the final outcome of the Regulation, if, a prior consultation with the national data protection supervisor has proven that the handing over of the data does not prejudice the interests of the persons whose data is included in the registers.

A3.5. The pan-European data protection regulation and Nordic research cooperation

It is still too early to tell what the final wording of the future General Data Protection Regulation will be, but given the time that has elapsed since the publication of the first proposal for the Regulation and the subsequent versions, it is possible to distinguish certain emerging basic principles regarding the processing of personal data for research purposes. Firstly, the processing should be based on the consent of the data subject. In relation to processing of personal data already collected for another purpose, data should be processed primarily in an anonymised form. Only if this is not possible may personal data be processed in a pseudonymous form, provided that data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information as long as the research purposes can be fulfilled in this manner. (Commission's proposal) According to Parliament, pseudonymisation should be carried out under the highest technical standards, and all necessary measures must be taken to prevent unwarranted re-identification of the data subjects. (Parliament Resolution)

Most importantly, with regard to register-based research in the Nordic countries, the Parliament Resolution provides for the application of national freedom of information legislation together with the General Data Protection Regulation to determine whether personal data from public registers can be used for research purposes. This would mean in practice that if the national freedom of information law permits the processing of personal data for research purposes subject to the data protection law, it could be done when the data is anonymised or pseudonymised according to the requirements of Article 83 of the Regulation.

With regard to processing of health data for research purposes, the Regulation gives the Member States the possibility to provide for exceptions to the requirement of consent for the use of health data for research if the research serves a high public interest and cannot possibly be carried out otherwise. The Nordic countries could seize this as an opportunity to harmonize their national laws in this respect. If the Nordic laws and practices were in-synchrony as to how to define research that serves high public interest and under what circumstances personal data relating to health could be used for research in such cases, this would constitute sound legal basis for building-up a common Nordic data sharing framework.

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