

# New legislation – a unique opportunity for harmonising the legal framework for research in the Nordic countries

Position paper on the importance of and opportunity for harmonised and research friendly implementation of the General Data Protection Regulation (GDPR), to facilitate open access and data sharing across Nordic borders.

## By

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## The Nordic network-project

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## Executive summary

The registers in the Nordic countries are a goldmine for research, and give the Nordic countries an opportunity to play a pivotal role in international scientific research. However, the differences in the legal frameworks, strict legal practice and unnecessary bureaucratization in the Nordic countries are great obstacles for research collaboration and data sharing across Nordic borders. With the implementation of the GDPR the Nordic countries now face an unprecedented possibility: to create a common legal framework that not only allows, but incentivises cross-national research through trust, structure, common legislation and harmonised practice. This is a unique opportunity that we encourage the Nordic ministries to take full advantage of.

We encourage the Nordic ministries to remember the importance and value of Nordic scientific research, especially register-based research, when drafting the national laws. All legislation intends to serve a normative function. As such, good and explicit conditions for research will send a clear signal that research is an important activity in the interest of society; and is therefore granted a privileged position in the law. Unambiguous wording with regards to the status of scientific, statistical and historical purposes within the privacy regulation is paramount in establishing that privacy protection and access to personal information for scientific purposes can go hand in hand. This should also give a clear signal to institutions that over time will give substance to the law and stipulate the conditions for storage, use and disclosure of personal data.

## Introduction

The General Data Protection Regulation, EU Regulation 2016/679 (GDPR) focuses on the protection of personal data and the free movement of such data, and is set to replace the EU Data Protection Directive (94/46/EC) from 25 May 2018. The aim of the new law is: to harmonise privacy legislation throughout the EU/EEA; to make it easier to share data across borders; and to update the legislation in order to make Europe fit for the digital age. It also aims to ensure consistent high-level data protection, to guarantee legal certainty and establish a foundation of trust by providing citizens' rights to privacy. Privacy regulations have high impact on national, Nordic and European research and the implementation of the GDPR is therefore of great interest to the Nordic research community.

The general impression of the GDPR is one of protection of the interests and needs of the research sector. As the GDPR is a regulation and not a directive the amount of flexibility in its application is limited. However, there are derogations where national authorities can exercise discretion over how certain provisions will apply. The research provisions in the new law are one of the areas with most flexibility, thereby providing room for idiosyncratic national adaptations. This has raised concerns that the conditions for research can become more restricted than necessary and that the conditions and practices related to the processing of personal data for research purposes will still vary between countries. The research communities fear that this will counteract the EU's efforts to achieve harmonised legal conditions for research across Europe and thus lead to a continuation of current difficulties for research collaboration and data sharing across borders, in particular with regard to register based research.

## Nordic network project for a research friendly and harmonised implementation of the GDPR

Against this background, Norway, currently holding the Presidency of the Nordic Council of Ministers, has funded a Nordic network-project led by NSD - Norwegian Centre for Research Data in cooperation with the Swedish National Data Service (SND), The Danish National Archive (DNA incl. Danish Data Archive (DDA)) and the Finnish Social Science Data Archive (FSD). Legal advice is provided by Nordforsk.

The aim is to recommend and encourage the Nordic ministries to endeavor to contribute to a harmonised and research friendly implementation of the GDPR in order to enhance the conditions for research collaboration and data sharing across Nordic borders.

As part of the project an expert workshop was held in Bergen 19th of April 2017, where a group of researchers with first-hand experiences from the medical and socio-economic field, as well as experts from ethics committees and data protection officials, were invited to present and discuss existing and new possibilities and obstacles for Nordic research collaboration, with a specific emphasis on register-based research and data sharing across borders. This position paper is an outcome of the workshop, aiming to pinpoint critical barriers to data access and sharing across the Nordic borders from the researchers', the experts' and the Nordic data network project's points of view. Additionally the paper will provide advice on opportunities that now exist for a harmonised legal framework and suggestions for improved conditions for research in the GDPR.

The Nordic Microdata Access Network (NordMAN), was invited to present their work to improve access to Nordic microdata.<sup>1</sup> Please see the attached agenda for information about presentations and participants.

The Nordic countries have recently drafted their proposals for new national data protection legislation to complement the GDPR. These have been published for public consultation. The proposals are suggested as supplements to the GDPR in areas where the GDPR allows for national variation. Sweden has also proposed a Research Data Act that shall apply to all processing of personal data for research purposes in addition to that set out by the Data Protection Act. Deadlines for public consultations in the Nordic countries are:

- Denmark- 22<sup>nd</sup> August 2017
- Finland - 9<sup>th</sup> September 2017
- Norway – 16<sup>th</sup> October 2017
- Sweden – 15<sup>th</sup> September 2017

The Nordic network-project will deliver a second position paper later this fall. The main focus in the next paper will be on the provisions in the proposed new national legal framework that

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<sup>1</sup> The NordMAN project is a cooperation between the Nordic NSI's funded by NordForsk. The project's main objectives are to implement common procedures, administrative processes, security rules and to provide trustworthy information on whether the relevant data exist and if the data is comparable between the Nordic countries. More information can be found here: <http://nordman.network/>.

may influence data sharing across the Nordic borders and conditions for Nordic cross country research.

### **Nordic Registers – a goldmine for research**

The Nordic countries have a long tradition of and extensive experience with register-based statistics and research, having kept central population registers since the 1960s. There are well-established administrative registers, national health and quality registers, longitudinal databases and biobanks in all Nordic countries. The registers cover the entire national populations and can be linked through a personal identification number for each citizen. The Nordic region would be unique if the existing population-based registers and biobanks could be utilized in a coordinated way. Together the Nordic population amounts to 26 million people, which allows comparative and demographic studies as well as studies of rare diseases. This gives the Nordic countries an opportunity to play a pivotal role internationally for several types of research of high scientific and societal value, rooted in data sharing and research cooperation.

Nordic countries are known as world leaders in providing access to microdata for research. However, cross Nordic register-based research is still very rare and the Nordic registers clearly constitute a goldmine that is not utilized to its full potential. Increased Nordic research on urgent societal problems is important to address future societal challenges with efficient and cost-effective solutions for the development of healthcare and welfare systems. Additionally, the Nordic registers constitute great potential for researchers from outside the Nordic countries, as comparable quality and details are missing from registers in other national contexts. A legal framework for data sharing must obviously be put in place in order to take advantage of this opportunity. In fact, the GDPR calls for this.

### **Obstacles for register-based research and data sharing across borders**

Register-based research is prominent in the Nordic countries. However, the Nordic goldmine of data resources remains underexplored largely due to cumbersome legal, ethical, organisational, and technical constraints. In this paper the focus is on how law and legal practice limits register-based research, in particular across borders, as reported at the workshop in Bergen.

### **Permission for data pooling**

In all Nordic countries the current legal framework that regulates data collected by public institutions for administrative and/or statistical purposes allows for dissemination of data for research purposes, including cross-border research, given that appropriate safeguards and guarantees are in place. Nevertheless, when applying for access to data researchers experience that the register owners adhere to legal practices that ultimately hinder their plans for pooling data across Nordic borders. A common complaint is that it is especially difficult to get permission to pool socioeconomic variables<sup>2</sup> across borders. The Statistics act may open for dissemination and sharing of data, but the Nordic statistical agencies' current interpretation

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<sup>2</sup> Some of the researchers participating at the workshop added that it is often much more straight forward to get access to data from the health registers. This in itself seems peculiar as one could get the impression that socioeconomic data are viewed as more sensitive than health data.

and practice vary.<sup>3</sup> As a consequence, Nordic comparative research that includes socio-economic variables is usually based on aggregated data, and comparison is usually done by separate analyses of national datasets and then comparing the results.<sup>4</sup> This clearly restricts the scope and depth of the research and consequently knowledge of public utility produced from Nordic register-based research.

### Need for review of national statistical legislation

An important issue is therefore to consider a review of national statistical legislation in light of the new data protection legislation, to improve both national and cross-national (Nordic) research. The same applies for the legislation regulating health research. To ensure harmonised legislation and legal practice in line with the intentions of the GDPR, it should therefore be explicated in the laws that it is legal to disseminate and share personal data across borders, on condition that appropriate safeguards are in place.

### Unfit access procedures and practices

Another obstacle reported by participants at the workshop is that getting access to data is increasingly costly and time consuming.<sup>5</sup> Current legal framework requires that a researcher needs to obtain a permit from each register, and often in addition ethical committees, data protection authorities and authorities that can set aside duty of confidentiality. Each authority requires information about the project with descriptions and justifications for the processing of personal data. In addition, all authorities require a copy of the applications sent to other authorities.<sup>6</sup> When assessing applications the different authorities often request specific terms for processing or demand changes to be made before permission is granted. If changes are made, the other authorities must be notified. It goes without saying that the conditions for comparative cross national research is even more challenging, as the laws vary and requirements for obtaining different permissions multiply.

This increased bureaucratisation has become both a financial and temporal burden on the research community. Many researchers use up to one or two thirds of their allocated time in a project applying for access to data and then on cleaning the datasets, which leaves little time for analyses and presenting findings in articles and reports. As one researcher put it: "The dream has become a nightmare." Ultimately one question rises to the surface: does this bureaucratisation and repeated assessment by numerous agencies actually provide any increase or improvement in data protection, when agencies are all assessing the same issues; the societal benefits of the project against the risk to the data subjects' privacy? Based on the experience of the group this repetition of evaluations and assessments of a single project is

<sup>3</sup> For instance the Norwegian regulations contain exemptions stating that the Nordic statistical agencies can be used as a basis for giving researchers in other countries access to de-identified microdata, as stated in a report from the Nordic Chief Statisticians' Meeting 4-5 September 2014 in Helsinki.

<sup>4</sup> There are exemptions The project Socioeconomic Consequences in Adult Life after Childhood Cancer in Scandinavia (SALiCCS) is a best practice example. At the workshop the project leader presented how they managed to obtain permissions to pool data from three Nordic statistical bureaus. The project has also been a pilot project NordMAN (Nordic Microdata Access Network). <http://nordman.network/>

<sup>5</sup> A researcher explained how for instance, in Denmark it used to be enough to apply for permission from the Data Protection Authority and the National Board of Health. The researchers received a single permission for universal use. It normally took 1-2 days to fill out forms and get permission, a few months to get data and the cost was between 5000-35 000 DKK. Today researchers need several permissions, and the number and length of forms that needs to be completed have increased. Researchers report using 2-3 weeks on completing the various application forms. In addition, the cost has increased to 15 000-55 000 DKK.

<sup>6</sup> For instance, in Norway one is required to obtain a permit from the Data Protection Authority, as well as one or more additional permits from other (exempting) agencies and authorities, as well as from the registries administrating the data. The result is that one researcher may end up having to write up to ten applications that are all more or less identical.

needless. It only results in a reduction of time available to researchers to conduct the actual research, and any benefit is negligible where it concerns privacy and data protection.

### **One stop shop for Nordic research projects**

Therefore, an important task for the Nordic ministries when implementing the GDPR is to dismantle unnecessary bureaucratic obstacles within and between countries. One step in this direction is to make it explicit in the new legislation that one data protection impact assessment from one Nordic country is sufficient for data owners to grant access to cross-border processing of personal data for scientific research purposes. This is in line with the intentions of the so called one-stop-shop in the GDPR.

### **Unique opportunity for harmonising the legal framework for research**

The GDPR gives the Nordic countries a unique opportunity to harmonise their legal framework, and to improve the conditions for research and cross-border data flow. The rationale behind the new regulation is indeed to ensure the same level of data protection throughout the EU/EEA in order to make it easier to share data across borders. Thus, the GDPR has a limited flexibility in its application. Nevertheless, there is room for national derogations, and this possibility for supplementary provisions applies especially to the field of research. This represents both risks and opportunities.

The overall message from the participants at the workshop in Bergen is that the Nordic ministries should use this unique opportunity to ensure a research friendly, harmonised and unambiguous legal framework for research. A crucial element in this regard is to limit the scope for national discretion by implementing the same national derogations and provisions to as large a degree as possible in the new national data protection regulations and related special legislation. This will provide equal conditions for research in the Nordic countries, and improve the possibilities for personal data to be processed and shared within each country and across the Nordic borders for research purposes. The articles where countries can exercise discretion and where the Nordic ministries must endeavor to protect the interests of the research community are as follows:

#### **The free movement of personal data within the Union – Article 1 (3)**

The free movement of data in the Union is already covered to a great extent by Article 1 3. We ask the national ministries to review which existing national legislation must be removed or altered in order to comply with Article 1.3. This is also in line with the Union's objective of realizing a European research area under Article 179 (1) of the Treaty on the Functioning of the European Union (TFEU).<sup>78</sup>

#### **Derogations from data subjects' rights - Article 89 (2) and (3)**

Article 89 (2) and (3) of the GDPR allow union or member state laws to create derogations from the data subjects' rights where personal data are processed for research and/or archiving purposes subject to the conditions and safeguards referred to in Article 89 (1). We advise the

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<sup>7</sup> The Union shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapters of the Treaties (Article 179 (1)).

Nordic countries to make full use of these derogations. It is our view that these derogations should be treated as uniformly as possible by the Nordic countries.

### **Appropriate safeguards - Article 89 (1)**

The exemptions for archiving and research purposes require appropriate safeguards to be implemented in line with Article 89 (1). We are worried that the Nordic countries may adapt different safeguards which in turn may constitute a breach of Article 1(3) and thus cause unnecessary hindrance to bring about a common European Research Area. This would require scrutiny of safeguards from several countries and evaluating not only the safeguards but the territorial scope of the national laws.

### **Data Protection Impact assessment (DPIA) - Article 35 and 36**

We also recommend the Nordic Data Protection Authorities to cooperate when defining what types of research projects would require an impact assessment (“pre-approval”) as covered in Article 35 and 36 of the GDPR. In Finland, for example, all projects utilising sensitive data or data relating to criminal convictions would be subject to DPIA.

### **Lawfulness of processing – Article 6, 1 (e)**

The GDPR allows Member states to maintain or introduce more specific provisions when using public interest in Article 6, 1 (e) as lawful basis for processing of personal data for research purposes. Article 6 paragraph 3 states that public interest as lawful basis shall be laid down by Union or Member state law. We call upon the Nordic governments to explicitly state archiving and research as important tasks carried out in the public interest in their national laws. This to ensure research is defined as a matter of public interest, thus giving research a clear legal basis.

### **Processing of special categories of personal data - Article 9**

Processing of special categories of data is in principle prohibited, but can be carried out if based on consent or other legal bases. The one most relevant for research purposes (in addition to consent) is Article 9 (j). According to Recital 52, research serves as a basis for processing sensitive data only “when provided by Union or Member State law and subject to suitable safeguards.” In addition Article 9.4 allows member states to introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health. However the possible conditions/limitations in Article 9.4 are subject to the requirement for providing free movement of data in order to establish a European Research Area.

We call upon the Nordic governments to ensure that Member State laws explicitly mention that archiving purposes in the public interest and scientific research purposes are legitimate purposes for which sensitive data can be processed. Furthermore, we recommend to not introduce any further conditions or limitations for the processing of health data for research purposes, as Article 9.4 allows for.

### **Processing of data relating to criminal convictions and offences - Article 10**

Processing of personal data relating to criminal convictions and offences or related security measures based on Article 6.1 can only be carried out by official authorities or when the processing is authorised by Union or Member State law. We urge the Nordic ministries to

ensure that Nordic national laws allow data about criminal convictions and offences to be collected and/or disseminated for research purposes on the same basis as other special category (personal) data, in line with the suggestions above.

### **Processing of national identification number - Article 87**

Member States may determine the specific conditions for the processing of a national identification number or any other identifier of general application. We call upon the Nordic ministries to ensure that no limitations or conditions are introduced for research purposes as processing of personal identification numbers are crucial to register based research.

To avoid different legal framework in the Nordic countries when drafting national laws supplementing the articles mentioned above, we encourage the Nordic ministries to:

- Make it explicit that it is legal to share personal data across borders on condition that appropriate safeguards are in place.
- Provide a clear legal basis for creating pooled data sets for Nordic research projects, for instance when revising statistics legislations, and other laws that the GDPR will interact with.
- Make it explicit that a single Nordic country's approval is valid for cross-border processing of personal data for scientific research purposes.
- Ensure the viability of cross-border research projects, and to maintain this (possibility) through national legislation, ensuring that this new legal framework will prepare for and provide support for achieving a Nordic as well as a European Research Area.
- Clarify legal requirements and possibilities for interpretation of the GDPR.
- Explicitly state archiving in the public interest and scientific research as important tasks carried out in the public interest in their national laws.
- Harmonise legislation for utilizing register-based data for research purposes across the Nordic region.

### **Summary: unique opportunity to create a Nordic research area**

The registers in the Nordic countries are a goldmine for research, and give the Nordic countries an opportunity to play a pivotal role in international scientific research. However, the differences in the legal frameworks, strict legal practice and unnecessary bureaucratization in the Nordic countries are great obstacles for research collaboration and data sharing across Nordic borders. With the implementation of the GDPR the Nordic countries now face an unprecedented possibility: to create a common legal framework that not only allows, but incentivises, cross-national research through trust, structure, common legislation and harmonised practice. This is a unique opportunity that we encourage the Nordic ministries to take full advantage of.

We encourage the Nordic ministries to remember the importance and value of Nordic scientific research, especially the register-based research, when drafting the national laws. All legislation intends to serve a normative function and good and explicit conditions for research will send clear signals that research is an important activity in the interest of society, and therefore is granted a privileged position under the law. Unambiguous wording with regard to the status of

scientific, statistical and historical purposes in terms of the data protection regulation is paramount in establishing that privacy protection and access to personal information for scientific purposes can go hand in hand. This should also give a clear signal to institutions that, over time, will give substance to the law and stipulate the conditions for storage, use and disclosure of personal data.

Attachment: Agenda Workshop, Wednesday 19 April 2017

# Agenda Workshop, Wednesday 19 April 2017

## Time

09:00 - 09:10 **Welcome and tour the table**

09:10 - 09:25 Vigdis Kvalheim Presentation of the Nordic cooperation project

09:25 - 09:55 Marjut Salokannel Data protection and research in the Nordic countries – a legal perspective

09:55 -10:05 Magnus Stenbeck Research and the General Data Protection Regulation  
Some aspects from a Swedish perspective

10:05– 10:15 Tom Southerington Barriers and possibilities for Nordic research  
collaboration – an ethics committee’s perspective

**10:15-10:30 Break**

## **Barriers and possibilities for Nordic research collaboration – researchers’ perspectives**

10:30 - 10:45 Merete Osler Barriers and possibilities for epidemiologic research  
and collaboration – a researchers’ experience

10:45 – 11:00 Thomas Lorentzen Barriers and possibilities for Nordic research  
collaboration – researchers’ perspectives

11:00 -11:15 Svetlana Solovieva Nordic occupational register: a tool for estimation of  
the potential of workplace and population level  
interventions

11:15 – 11:30 Jeanette Falck Socioeconomic Consequences in Adult Life after  
Winther Childhood Cancer in Scandinavia (SALiCCS).  
Possibilities and barriers for data collection and data  
sharing in the Nordic countries

**11:30 – 12:30 Lunch**

12:30 -12:45 Magnus Stenbeck Register based research and data protection in the  
future

12:45 -13:00 Claus-Gøran Hjelm, NordMAN: The Nordic Microdata Access Network

## **Impact of GDPR – new possibilities/barriers for research**

13:00 – 14:30 Plenary discussions

14:30 - 15:00 Summary and recommendations

## Participants:

Name	Profession/position	Institution	Country
Jeanette Falck Winther	Head of the Childhood Cancer Survivorship Research Group/ Project leader: Adult Life after Childhood Cancer in Scandinavia (ALiCCS): Socioeconomic consequences of long-term survival.	The Danish Cancer Society	Denmark
Merete Osler	Clinical Professor	Department of Public Health, University of Copenhagen	Denmark
Anne Sofie Fink Kjeldgaard	Head of Research Data Dissemination Services	The Danish National Archive	Denmark
Svetlana Solovieva	Researcher/ Project leader: Nordic Occupational Register – a tool for estimation of the potential of workplace and population level interventions	Finnish Institute of Occupational Health Helsinki	Finland
Tom Southerington	Director	REC from The Hospital District of Southwest Finland (Turku)	Finland
Kirsti Husgafvel-Pursiainen	Professor	Finnish Institute of Occupational Health Helsinki	Finland
Marjut Salokannel	LL.D., Adjunct Professor	SaReCo/Nordforsk	Finland
Arja Kuula- Luumi	Development manager	Finnish Social Science Data Archive/University of Tampere	Finland
Kjetil A. Van der Wel	Associate Professor	Faculty of Social Sciences, Oslo and Akershus University College of Applied Sciences	Norway
Thomas Lorentzen	Professor	Department of Sociology, University of Bergen	Norway
Vigdis Kvalheim	Deputy Director	NSD - Norwegian Centre for Research Data	Norway
Inga Brautaset	Special Advisor	NSD - Norwegian Centre for Research Data	Norway
Marianne H. Myhren	Senior Advisor	NSD - Norwegian Centre for Research Data	Norway
Magnus Stenbeck	Senior Researcher/ Sekreterare Forskningsdata-utredningen	Department of Clinical Neuroscience (CNS), Karolinske Institutet	Sweden
Claus-Göran Hjelm	Project leader NordMAN	Statistics Sweden	Sweden
Max Petzold	Director	Swedish National Science Data Archive	Sweden