

## **GUIDELINES FOR THE DISTRIBUTION OF DATA FROM THE NORWEGIAN PATIENT REGISTER**

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## I. Introduction

These guidelines provide guidance and information for researchers and others who are seeking access to patient information. The Norwegian Patient Register (NPR) distributes data to everyone who applies for such data if the conditions for disclosure are met. The NPR maintains an overview of everyone who receives information, what the information will be used for and the authorisation basis for release of the data. Data from the NPR is developed in order to help improve our knowledge of health services, treatment and medical conditions, which in turn will help improve the health service and health policy. These guidelines are intended to help ensure that data is made available in a secure manner from a privacy perspective and in accordance with applicable laws and regulations.

## II. Purpose of the Norwegian Patient Register

The use of data in line with the purpose is important for the legal protection and privacy of those who are registered.

Information from the NPR can therefore only be used as a result of the purposes in accordance with the Norwegian Patient Register regulation,<sup>1</sup> Section 1-2:

- to form the basis for the administration, management and quality assurance of specialist health services, including activity-based financing
- to contribute to medical and health research, including research which can give knowledge concerning health services, treatment effects, diagnoses and the disease's causes, distribution and development and preventive measures.
- to provide a basis for the establishment and quality assurance of disease and quality registers
- to contribute to knowledge as a basis for the prevention of accidents and injuries

## III. What can be disclosed?

It is possible to obtain statistics and anonymous information, de-identified information and personally identifiable information. It is also possible to obtain data that has been produced through links with certain other registers.<sup>2</sup>

It is also possible to obtain information from the NPR for the period 1997 to 1 March 2007, when NPR was run as a de-identified register with a concession from the Norwegian Data Inspectorate. However, this data contains no information on patient identity and it is also not possible to track patients between hospitals and between years.

The more basic data that can be obtained consists of statistical and anonymous information. It is also possible to obtain de-identified information. Stricter requirements apply to de-identified information. Personally identifiable information can also be obtained. In these cases, a concession from the Norwegian Data Inspectorate and derogation from the medical personnel's duty of confidentiality are generally required. For the release of personally identifiable information for medical and health research, the concession obligation and requirement for derogation from the duty of confidentiality is replaced by advance approval from a Regional Committee for Medical and Health Research Ethics. Information on the data that is available is given below.

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<sup>1</sup> FOR 2007-12-07 No. 1389: Regulation on the collection and processing of medical information in the Norwegian Patient Register (the Norwegian Patient Register Regulation), hereinafter referred to as 'the Regulation'.

<sup>2</sup> See item XII.

## IV. Application for access to information

The NPR plays an important role in the dissemination of data, either in the form of statistics or as data as a basis for research and investigation. To ensure that the NPR's dissemination of data is carried out in accordance with applicable regulations, formal decisions are taken concerning the release and linking of all data. This means that everyone who wishes to obtain data from the NPR must apply to do so.

An important restriction on the use of data from the NPR is that the data can essentially only be used for the expressly stated purposes pursuant to Section 1-2 of the Regulation. Applicants must therefore demonstrate that the planned use of information from the NPR falls within the purpose of the NPR.

Authorisation to release data follows from Sections 3-3 to 3-7 of the Regulation. Here, a specific assessment must be made in each case as to whether the conditions for release of the data are met.

The conditions for the release of the various types of data are described under the following sections, VIII, IX and X. The linking of data will be discussed under section XII.

## V. Application form

Everyone wishing to obtain data from the NPR must complete our application form. This form is our principal tool for processing applications for the release of data correctly, quickly and efficiently. Applicants must read the guidelines for the release of data from the Norwegian Patient Register before completing the application form. It is important that the application form is completed fully, as the application process may be delayed if there are any omissions. It is also important that all necessary permits are attached with the application.

Applications must be submitted electronically and can be found on the NPR's website [http://www.helsedirektoratet.no/norsk\\_pasientregister](http://www.helsedirektoratet.no/norsk_pasientregister)

## VI. Release of information for the period before the Norwegian Patient Register Regulation was adopted

The NPR has existed as a de-identified register with a concession from the Norwegian Data Inspectorate since 1997. It is still possible to obtain data from the Norwegian Patient Register for the period 1 January 1997 to 1 March 2007. Out of consideration for the time series, the NPR will continue to produce de-identified files for the activity in 2007 and 2008. This means that external users of data from the NPR can obtain data on the activity within the specialist health service from 1997 through to the most recent data which has been quality-assured as national data files in the NPR. If comparable data for the entire period is required, this will necessarily be data where activity cannot be linked to individual patients between years or between hospitals.

The Personal Health Data Filing System Act was amended as of 16 February 2007 in order to permit the registration of direct personally identifiable characteristics in the NPR. The legislative changes have no retrospective force. This means that the NPR can only contain personally identifiable medical information for patients whose treatment began after 1 March 2007.

Users of data must therefore consider whether they require de-identified data for the entire period, or personally identifiable data from the period for which this data is available. It is also possible to provide personally identifiable data from the date on which it began to be registered, combined with de-identified data for the entire period. However, neither the NPR nor recipients of data are permitted to collate information on patients via a process of

indirect re-identification across the two data sets. If this is done, the preconditions that legislative amendments are not to have retrospective force will be breached.

The application form must state clearly whether data is required in the "old" de-identified format, or in the new personally identifiable format. This must be assessed against the purpose of the release of the data.

## VII. Processing and release of information for activity-based financing schemes

Section 3-3 of the Regulation regulates the release of information by the NPR for established activity-based financing schemes. The principal aim of the NPR is to contribute to the administration, management and quality assurance of specialist health services. There will be a need to obtain regular access to information from the NPR for the activity-based financing scheme. The NPR will process and release information to the Directorate of Health. Only information that is necessary for the operation and development of established activity-based financing schemes must be released. The information must be relevant and necessary for the performance of the tasks concerned.

The information that is released must be deleted as soon as the tasks have been completed and no later than five years after the end of the operating year. If older data is required for comparative purposes or similar, the information must be released in accordance with Section 3-4, Section 3-5 or Section 3-6.

## VIII. Release of statistical and anonymous information

Upon request, the NPR will release statistics and anonymous information which has been produced with the aid of data from the NPR. In accordance with Section 3-5 of the Regulation, the Norwegian Patient Register is obliged to release statistics from the NPR and statistics of collated information in accordance with Section 3-1 or anonymised data upon request. This obligation presupposes that the information will be used for an expressly stated purpose within the NPR's purpose; see Section 1-2 of the Regulation.

Statistics and anonymous information fall outside the scope of the Personal Health Data Filing System Act and the Personal Data Act. Information is not covered by the duty of confidentiality.

## IX. Release of de-identified information

It is possible to apply for de-identified information from the NPR. It is also possible to apply for the NPR to be linked to certain other registers (see below) before data is de-identified and released.

Recipients of de-identified data do not need to apply to other bodies such as the Norwegian Data Inspectorate or a Regional Committee for Medical and Health Research Ethics in order to obtain data. Data recipients are obliged to notify the Norwegian Data Inspectorate in connection with such releases.

De-identified medical information is medical information from which names, national ID numbers and other characteristics unique to individuals have been deleted, so that the information can no longer be linked to an individual person, and where the person's identity can only be traced through a summary of the same information that was removed previously. In this regard, one of the main differences between anonymous information and de-identified

information is that de-identified information has a link key. However, when such information is released, it must be just as completely anonymous once it has been received by the recipient.

The release of de-identified information can present special challenges. A specific assessment must be made in each case as to whether the information is considered to be de-identified. Even where normal practice for de-identification has been followed, there may still be cases where following a more detailed assessment, data can still be considered to be insufficiently de-identified.

A discretionary line must be drawn in relation to the amount of work that would be necessary in order to link information to a person. The question can be considered on the basis of all the tools that can reasonably be used to identify the person concerned. If no great amount of work and/or expenditure would be necessary to link the information to a particular person, this may indicate that the information has not been sufficiently de-identified.

The same would apply if there is uncertainty as regards which individual certain information is linked to. This would apply for example if the people concerned belong to the same household/family.

The more serious the possible privacy violations are, and the more resources that are required to identify individuals will be strong considerations, without the information necessarily falling outside the definition of 'personal data' for that reason. Factors that must be taken into consideration are whether it is possible to find out who the person is by chance.

Applications for the release of de-identified information for medical and health research must contain information on the person responsible for the research and the project leader; see Section 6 of the Health Research Act. In the case of applications for de-identified information for this purpose, the NPR may, when in doubt as to whether processing would raise any objections from an ethical perspective, refer the question of whether to release the data to a Regional Committee for Medical and Health Research Ethics.

### ***Further considerations relating to de-identification***

De-identified data should generally be anonymous once received by the recipient. Anonymous does not simply mean that the national ID number has been deleted; it also means that it is not possible to identify individuals on the basis of other information. In the NPR, it will often be possible to identify patients based on information concerning age, gender, home municipality and date of admission. If you know in advance when a particular person was admitted to hospital and you can only find one person in the NPR with the right age, gender and time of admission, you can be certain that you have found this particular person in the data material. It will then generally also be possible to find information on the person's medical status, even if you do not know the reason for the admission in advance. This form of identification is normally known as 'indirect re-identification'.

The NPR is responsible for de-identifying or anonymising the personal data that is released in accordance with the provisions set out in applicable laws and regulations. There are three reasons in particular why de-identifying data from the NPR may be difficult. Firstly, the register contains a considerable amount of administrative information on each stay in hospital. This means that it is very likely that the information concerning a hospital stay is unique to a particular patient. Secondly, the NPR contains information on all patients who have been treated within the specialist health service during a period of time. This means that, when you recognise a patient in the NPR using information concerning gender, age, home address or similar, you can be certain that this is the only patient in Norway who has these characteristics. Thirdly, we have many treatment centres within the specialist health service, so that the number of patients per treatment centre is relatively low. This means that

many of the patients in the NPR are registered with information that is unique to them and only them.

These considerations mean that when anonymising data it is necessary to delete and/or group many variables. The assessment of how this should be done must be carried out in close collaboration with the environment that will use the data for research or analysis purposes and will partly depend on the theory and method which will be used by the individual project. Municipal authorities can for example be grouped under the health trusts' intake areas, year of birth can for example be grouped into 10-year age groups, diagnoses can for example be reduced to the first letter in ICD-10 and dates can be replaced by estimated figures for waiting time, bed occupancy times, etc.

It is however important to emphasise that it will be necessary to extensively delete and/or regroup data in order to ensure that the data material really is anonymised. Even after such a process, there will often be a limited number of hospital stays which are unique (e.g. a patient in the age range 60-70 resident in the Finnmark Health Trust area who has been treated by Ringerike Health Trust). Such hospital stays must be deleted from the data prior to release. The Norwegian Patient Register will generally delete or regroup units (patients) if there are four or fewer absolutely identical units (patients) in the data that is to be de-identified.

There is nevertheless a possibility that an adequate degree of anonymisation will still not be achieved. A discretionary assessment must be made in each individual case and the NPR will strive to do this in a dialogue with the party that is requesting the data.

If it becomes too difficult to de-identify data for research purposes, it is an alternative to release data which contains so much information that is personally identifiable. However, the release of such data requires a concession from the Norwegian Data Inspectorate. In addition to a concession, derogation from the medical personnel's duty of confidentiality must also be obtained from a Regional Committee for Medical and Health Research Ethics. For the release of personally identifiable information for medical and health research, the concession obligation and requirement for derogation from the duty of confidentiality is replaced by advance approval from a Regional Committee for Medical and Health Research Ethics.

A balance must be struck in each case as to whether it is appropriate to request de-identified data directly from the NPR or to apply for the necessary permits to receive personally identifiable data.

Another alternative is for the NPR to produce statistical tables to order for a research or study group.

## X. Release of personally identifiable information

If it is necessary for the purpose, it is also possible to obtain personally identifiable data from the NPR. 'Personally identifiable information' means both information linked to national ID numbers and information that does not fulfil the requirements for de-identification in accordance with Section 3-4.

In some cases, it may be necessary with so many variables that the information must be considered to be personally identifiable even though the national ID number and other characteristics unique to individuals have been removed (indirect re-identification). This applies to data from the NPR alone and may also apply to data that is linked to other

registers before release. In other cases, it will be necessary to release national ID numbers for the collation of data to which the research groups have access.

Section 3-6 of the Regulation authorises this type of release.

The processing of medical information requires a separate basis for authorisation; see Section 5 of the Personal Health Data Filing System Act and Section 33 of the Personal Data Act. The processing must also be carried out in accordance with the general rules concerning duty of confidentiality. Medical personnel are subject to a duty of confidentiality pursuant to the Health Personnel Act and the Public Administration Act, and the release of data requires derogation from the duty of confidentiality or the consent of the registered person. The applicant must also always state why it is necessary to use personally identifiable information.

The general rule is that the processing of sensitive personal information, including medical information, requires a concession from the Norwegian Data Inspectorate and a Regional Committee for Medical and Health Research Ethics to permit derogation from the duty of confidentiality in accordance with Section 35 of the Health Research Act. If the personally identifiable data to be released concerns medical or health research, the obligation to obtain a concession and the requirement for derogation from the duty of confidentiality is replaced by advance approval from a Regional Committee for Medical and Health Research Ethics; see Section 33 and Section 9 of the Health Research Act. In the latter case, the application must contain information on the person/entity responsible for the research and the project leader; see Section 6 of the Health Research Act. The applicant is also asked to attach the research protocol.

## XI. Processing of information in the Norwegian Patient Register linked to disease and quality registers

Section 3-7 of the Regulation specifically regulates the release of data from the NPR for the establishment and quality assurance of disease and quality registers<sup>3</sup>. Disease and quality registers provide information on the occurrence and treatment of delimited diseases.

Personally identifiable information may only be released for disease and quality registers if the register is authorised through either a concession or a regulation to use the Norwegian Patient Register as a basis. The information must be used for the establishment and quality assurance of information in a disease or quality register.

Information from the relevant register and the Norwegian Patient Register may be collated. However, the NPR cannot be supplemented with more variables than those that the NPR already contains; see Sections 1-6 and 1-7. Over and above this, Section 3-7 does not provide a basis for data processing, as it would be for a different purpose other than that which follows from the purpose, Section 1-2(2)(b).

Release for purposes other than the establishment and quality assurance of data must take place in accordance with Sections 3-4 to 3-6 of the Regulation.

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<sup>3</sup> See section 5.5 of Proposition to the Odelsting no. 49 (2005-2006) "Data basis for disease and quality registers".

## XII. Linking of data

As a general rule, the Norwegian Patient Register can be linked to other personally identifiable or pseudonymised registers. However, there are different rules for the release of linked data, depending on which registers are to be linked to the NPR and what is to be released after the link has been established.

The Norwegian Patient Register can release linked data in relation to statistics and anonymous information, de-identified information and personally identifiable information. In these cases, the requirements will be the same as those which follow for each individual release as referred to in sections VIII, IX and X.

Information in the Norwegian Patient Register can be collated with information in registers which are authorised pursuant to Section 3-1 and Section 3-2 of the Regulation.

- Cancer Register
- Medical Birth Registry
- Register of Causes of Death
- System for Vaccination Control
- Central Tuberculosis Register
- Notification System for Infectious Diseases
- Central National Registry
- Statistics Norway's socioeconomic registers<sup>4</sup>
- Prescription Register<sup>5</sup>

It is possible to obtain information from the NPR linked to other information from one or more of the abovementioned registers. This makes it possible to use variables over and above the Norwegian Patient Register's data set. The information that is collated must be delimited, relevant and necessary for an expressly stated purpose which is in line with the purposes of the Norwegian Patient Register.

Section 3-1 of the Regulation authorises the preparation of statistics. This means that the collation becomes anonymous information. In the event of release, a specific assessment must be carried out as to whether the information has been sufficiently anonymised and whether the statistics contain so many variables so that release must be refused, as it may be possible to recognise individuals.

Statistics must be released pursuant to Section 3-5.

Section 3-2(2) of the Regulation authorises the collation of Norwegian Patient Register data with the other registers referred to above, for the preparation of de-identified files. In this case, the collation will result in a de-identifiable data set. De-identified data should generally be anonymous upon receipt by the recipient. The collation must be in line with the expressly stated purpose within the purpose of the registers. Release must take place pursuant to Section 3-4.

It is also possible to link data to registers other than those referred to in Section 3-1, but a concession from the Norwegian Data Inspectorate and derogation from the duty of confidentiality, or possibly advance approval from a Regional Committee for Medical and Health Research Ethics, will then be required.

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<sup>4</sup> Socioeconomic registers primarily contain information on: income, national insurance, economic social assistance, demographics, education and work.

<sup>5</sup> When collating information from the Prescription Register, NPR data will be pseudonymised for collation with pseudonymous prescription register data. This applies in accordance with both Section 3-1 and Section 3-2. It will be the Prescription Register at the Norwegian Institute of Public Health (FHI) which will carry out the collation and release of data which includes the Prescription Register. Guidelines for the distribution of data from the Norwegian Patient Register

### XIII. Duty of confidentiality

In accordance with Section 15 of the Personal Health Data Filing System Act and Section 4-1 of the Regulation, anyone who processes medical information is subject to a duty of confidentiality in accordance with both the Public Administration Act<sup>6</sup> and the Personal Health Data Filing System Act<sup>7</sup>.

Recipients of information from the NPR are subject to a duty of confidentiality in relation to information that can be linked to individuals. The responsible handling and storage of medical information is therefore a precondition for the release of information. If the duty of confidentiality is breached, sanctions may be imposed in accordance with Section 7-2 of the Regulation.

The NPR has prepared a written contract, which must be signed before the data can be released. The contract covers a duty of confidentiality and the responsible processing of the information, as well as the return/deletion of the data.

### XIV. Consignments from the Norwegian Patient Register

The file format for deliveries from the NPR follow the format agreed in each individual case. Deliveries from the NPR will comply with the requirements concerning security measures that follow from Section 4-2. If national ID numbers are to be disclosed, the delivery will consist of two separate files, so that national ID numbers are not sent together with medical information.

### XV. How long does it take to obtain data?

The deadline for dispatch follows from Section 3-8 of the Regulation. According to the Regulation, dispatch must generally take place within 30 days from receipt of the application in accordance with Section 3-5, which concerns the provision of statistics and anonymous data. In accordance with the second paragraph, consignments of data collated with another register, de-identified data or personally identified data in accordance with Sections 3-4, 3-5, 3-6 and 3-7 must be dispatched within 60 days from receipt of the application. This assumes that a complete application has been received.

#### ***Exceptions from the deadlines***

The deadlines of 30 and 60 days may be extended if extraordinary circumstances make it impossible to reply. The applicant will then receive a preliminary reply stating the reason for the delay.

### XVI. Publication of work which contains data from the Norwegian Patient Register

It must always be stated that data from the NPR has been used. This also applies to summaries, press releases and search terms in official publication databases or similar.

### XVII. Fees for the provision of data

Fees linked to the provision of data from the NPR follow from Section 3-9 of the Regulation. The NPR may decide that the applicant should pay the costs associated with the collation

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<sup>6</sup> Act of 10 February 1967 on processing methods in administrative cases (the Public Administration Act).

<sup>7</sup> Act of 2 July No. 64. 1999 on health personnel etc. (the Health Personnel Act)  
Guidelines for the distribution of data from the Norwegian Patient Register

and provision of data that is being provided in full or in part. Working time spent forms the basis for fees linked to the provision of data. The fee may not exceed the actual costs attributable to such processing and provision of data.

Fees for the provision of data as of 2009 are calculated on the basis of an hourly rate of NOK 1100 excluding VAT, subject to a minimum fee of NOK 2200, excluding VAT. The fees can be adjusted annually.

## XVIII. Right of appeal

In accordance with Chapter IV of the Public Administration Act, decisions concerning the release of data may be appealed. Appeals must be sent to the Norwegian Patient Register. If the NPR decides not to amend the decision, it may be appealed before an overarching administrative body, which is the Ministry of Health and Care Services.

## XIX. Breach of agreement

If the conditions for the provision of data are not met, the Norwegian Patient Register reserves the right to assess the client's qualifications for using NPR data in the future. This applies to both individuals and organisations.

## XX. Definitions

The definitions follow from Section 2 of the Personal Health Data Filing System Act.

### Statistics

Statistical information is information that has been aggregated to form tabular data which cannot be linked to individuals. In practice, it is assumed that if the number of people in a group is fewer than five, the results must not be disclosed. A specific assessment of the type of variable must however be carried out.

### Data controller

The person who determines the purpose of the processing of the medical information and which means are to be used, unless responsibility for such data control is specially prescribed in the Act or in Regulations laid down pursuant to the Act.

### Data processor

The person who processes medical information on behalf of the data controller.

### De-identified medical information

Medical information from which names, national ID numbers and other characteristics unique to individuals have been deleted, so that the information can no longer be linked to an individual person, and where the person's identity can only be traced through collation with the same information that was previously removed. De-identified medical information must be anonymous to the recipient.

### Anonymous information

Information from which names, national ID numbers and other characteristics unique to individuals have been deleted, so that the information can no longer be linked to an individual person.

### Personally identifiable data

Personally identifiable information is information which includes personal identification (national ID number or name) or data which contains sufficient characteristics unique to individuals to indirectly identify individual persons.