17/10/2016

Export Form Guide

General info

A data export from the Swedish Neuroregister may only be used for the specific project that is specified in the export form, the project plan and ethical approvals granting use of data. Data may not be further used when the study is finished for follow-up studies and/or other projects that were not stated in the application for which you have been granted the export. If you want to go on with your study, you have to apply for another export or an amendment to the old application. When publishing results from your data export please enter www.neuroreg.se as data source in references and in acknowledgments if you get additional meaningful help over the basic data export.

The electronic export form replaces the old export form in a paper format. The electronic version makes it possible for us to update variable lists or other features so that you can have the latest information easily accessible.

The export form needs to be generated through the electronic form from now on (June 2016). The form will produce a pdf-file that is e-mailed to you (to the e-mail address you enter in the last step) for signature. Make sure the pdf is signed by the Investigator and sent together with the appropriate project plan and ethical approvals (if nessesary) to the person in charge listed at the end of the document. You can send the application either scanned by email or by postal mail.

Project name, Data manager, Investigator, Other involved persons and Institution

Provide a name for your project that describes your study. Avoid names like "project 2", its better with "Patients on Natalizumab, a cohort description" or something similar. Data manager is the person who will work with the data. This is the person to contact for answering specific questions. Examples: if a variable should be calculated as full years or with decimals, if overlapping treatments should be included or excluded and so on. Investigator is the person responsible for the whole study, usually responsible for ethical approval and/or study design and financing. Provide e-mail for both persons, these will not get any automatic e-mails. Other involved persons, provide names for the most involved persons. Institution, provide the name for the place where the Investigator have their main research activity.

Ethical Application(s) Approved

If your ethical applications are approved, choose "Yes" and provide the reference number(s). If you are awaiting approval, choose "No, awaiting response" and provide the reference number(s) if you have them. If an ethical approval is not needed, you must explain why. If you are applying for an export of data on your own patients for quality control and so on, ethical approval is perhaps not

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needed. In general, if results are going to be published in any way, ethical approval for using the data is needed even if you can export the data yourself (own unit/own patients).

Different types of limitations of data export

Under Group data you have the possibility to extract statistics on group level, for example the number of patients treated with a specific drug for 10 years or longer. No data on individual level will be provided. You can ask for a geographical limitation, for example only data on patients from Stockholm County or your own unit/units. Limitation in time of your cohort could mean that you only want data on patients that had an onset of disease between 2010-2014 or were treated with X between Y and Z, or similar cohort limitation. Under Other limitations you can specify what cohort should be extracted that is not covered above. For example, if you only want data on patients treated with a specific drug or if you want several cohorts to compare with each other and so on. Give us sufficient info or say that we need to contact you for more info if the extraction is complex. The data export team does not have access to the project plan!

Security of data

There are different types of anonymization. If you do not need the personal ID number (personnummer, pin) you should AVOID exporting it. You can choose 4 different levels of anonymization, all of them keep the relation thus you can track which data comes from what patient even though you do not have the specific pin. Total anonymization means that we will replace the pin with a random number-letter combination as ID and delete the connection key. This means that your export cannot be linked to any other source of data that use pin and you cannot go back and add on info to this specific export. You can ask us to keep this key so you can add on info to the same patients later on. You don't have access to the pin or key, but we store it safely for future use. Partly anonymized means that the registry ID is kept but you don't get the pin. This is useful if you need to go into the registry yourself to update data for quality work or similar issues. No anonymization is usually used when data needs to be accompanied with data from the electronic health records (EHRs) or when data needs to be sent to an institution i.e. The National Board of Health and Welfare (Socialstyrelsen) for merge of data. We will send the data directly to the institution and you will get data back from them when the merge is done. You can also specify some other type of anonymization if you wish.

Data merge and data sharing

It is very important to provide the info about with what other sources you will share the data. It has to be included and approved in the ethical applications.

Patient contact

If EHR will be used in any way, this must be disclosed and described here. Please describe if patients will be contacted in any way, how it is done and by whom.

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Variables to export

You have to choose from which registry you want to export data. Then you will see groups of variables. When selecting a variable group you can find several selections. You can always specify other variables that are not in the list or say that you want all of them. Please contact dataexport@neuroreg.se for more detailed variable lists. Make sure that the variables you want exported are mentioned in the project plan to avoid confusion.

Sending the PDF-file to the e-mail you provide

This is where you enter the e-mail to which the PDF-file of the export form will be sent.

Pressing the Send Button

This action sends the PDF to the above entered e-mail. After this you only have to print your PDF, make the Investigator sign it, scan and e-mail or send it by postal mail together with the project plan and ethical approvals (if needed) to the appropriate person:

MS-registry export, nation wide or
data outside your own clinic.
Professor Oluf Andersen
Neurosjukvården
Gröna Stråket 11, floor 3
Sahlgrenska Universitetssjukhuset
413 45 Göteborg
Telephone: 031-342 35 93
oluf.andersen@neuro.gu.se

MS-registry export, your own
clinic/patients.
Contact your local registry
representative at your clinic/center.

Narcolepsy registry export, all sorts
Anne-Marie Landtblom
Institutionen för neurovetenskap
Neurologi Akademiska sjukhuset
751 85 UPPSALA
anne-marie.landtblom@neuro.uu.se

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