

Information on Patients' Personal Data Processing in the ReMuS Registry

Dear Madam, Dear Sir,

we would like to hereby inform you that **ReMuS, Endowment Fund ("EF ReMuS")** processes selected personal data (including data on health) in the registry of multiple sclerosis patients in the Czech republic ("**ReMuS**"). The aim of the present document is to inform you – in accordance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC – about the processing of personal data in the ReMuS registry by ReMuS Endowment Fund.

Further information on personal data processing in the ReMuS registry and on its existence are available in the [*Information memorandum*] on www.multiplesclerosis.cz website. Alternatively, you can contact us via the below-listed contact details to obtain these information.

1. Purpose and Legal Basis of Personal Data Processing

Treatment of multiple sclerosis and other disorders

In the ReMuS registry, your personal data will be processed in order to support treatment of multiple sclerosis ("**MS**") and other neuroimmunological disorders ("**NIDs**"). In particular, the purposes are the following:

- monitoring prevalence of MS, Neuromyelitis optica disorder and its wider spectrum, MOG encephalomyelitis, and other NIDs,
- evaluating the epidemiological situation, i.e. information on: frequency, prevalence, and the course of MS and other NIDs, their clinical symptoms, attack rate, treatment (including the information on effectiveness of different medical preparations), disability, associated diseases, and causes of death,
- providing output which helps monitor the costs and effectiveness of health care and medical preparations,
- evaluating information addressed to health care payers, other public institutions, and manufacturers of medical preparations,
- evaluating seriousness of NIDs and their socioeconomic consequences,
- evaluating health risks for specific patients, and
- scientific and statistical purposes.

The legal basis for the processing of your personal data is in this case your explicit consent.

Informing about the ReMuS registry and the activities of ReMuS, Endowment Fund

To a limited extent, your personal data may also be processed for the purposes of informing about the ReMuS registry and the activities of ReMuS, Endowment Fund. This concerns especially situations in which the patients are informed about projects and results of the ReMuS registry, about related events, or in which the ReMuS registry and the activities of ReMuS, Endowment Fund are promoted in another way.

The legal basis for the processing of your personal data is in this case a) your consent, if you decide to grant it, or b) legitimate interest of ReMuS, Endowment Fund. The scope of personal data processing (the scope of addressing and the scope of the data processed, the possibility to withdraw consent or the right to object to personal data processing) differs based on the respective legal basis applied. Only if the legal basis is your consent, limited scope of health data may be also used for this purpose. In the opposite case, only identification data and contact data will be processed.

2. Categories of the Processed Data

ReMuS processes your personal data in the ReMuS registry to an extent which is necessary to fulfill the purposes mentioned above. In order to ensure that the connection between personal data in the ReMuS registry and the patient is not lost and that scientific validity of ReMuS is maintained, it is essential to process identification data, contact data, and other selected data alongside personal data related to MS or other NID (including special category data) in the ReMuS registry, too. The reason is traceability of individual patients (if they e.g. move house).

In particular, identification and contact data (for example first name, surname, address, telephone number, e-mail address, etc.), data on health, especially the scope of data which can be typically found in personal medical records (for example medical history, diagnosis, relapses, medical examination reports, doctor's visits, medical events, pregnancy, information on treatment, etc.), descriptive personal data (for example education, length of studies, employment, length of employment, information on social benefits), or data on finishing one's monitoring or changing the center for MS or other NID treatment ("**MS treatment center**") are all processed in the ReMuS registry.

3. Sources of Personal Data

Collecting personal data in the ReMuS registry predominantly takes place based on your regular visits in MS treatment centers, wherefore it will not require any extra time spent at your doctor's office, any expenses or special activities on your part.

The ReMuS registry may also acquire your personal data directly from you, especially if you do not visit any MS treatment center. The data can be sent through web interface, or using another method currently offered by REMUS, Endowment Fund.

Personal data acquired from public or non-public databases

If you grant your (separate) consent to it, public or non-public databases of information controlled by third parties, especially by selected (further listed) organizational structures of the Czech Republic or by government institutions, may be used as a supplementary source of your personal data processed in the ReMuS registry. The aim is to extend and enrich the data processed in the ReMuS registry, while the purpose of processing such data remains to be treatment of MS and other NIDs.

In this case, consent granted by the patient entails an inseparable body of activities consisting in conveying your basic identification data (especially your national ID number) to the controller of the respective database in order to identify you, analyze your relevant personal data in the particular database, and convey your selected personal data from the respective database controller to REMUS, Endowment Fund, and to the ReMuS registry. The respective database controllers will not participate in the personal data processing in the ReMuS registry in any other way, and after conveying the data to REMUS, Endowment Fund, an erasure of personal data processed specifically for this purpose will be performed.

Controllers of the databases to whom this consent to providing your personal data to the ReMuS registry applies are the following:

- Institute of Health Information and Statistics of the Czech Republic, CIN: 000 23 833; a database labeled National Health Information System, or another database that might replace it in the future, and also other databases containing information which may be relevant to treatment of MS or other NIDs
- State Institute for Drug Control, CIN: 000 23 817; various databases containing information which may be relevant to treatment of MS or other NIDs
- Ministry of Labour and Social Affairs of the Czech Republic, CIN: 00 55 10 23; various databases containing information which may be relevant to treatment of MS or other NIDs and social and economic consequences of these disorders
- Labour Office of the Czech Republic, CIN: 72496991; various databases containing information which may be relevant to treatment of MS or other NIDs and social and economic consequences of these disorders
- other institutions of government committed to similar affairs, or potentially other public or non-public databases whose use will be evaluated as beneficial to the purposes of personal data processing in the ReMuS registry, under the condition that the use of such database will be evaluated as beneficial by the Neuroimmunology and Liquorology Section of the Czech Neurological Society. In such instances, REMUS will publish the information about using the respective database on its website.

While granting your consent, you were informed that the ReMuS registry may be supplemented with your selected personal data relevant to treatment of MS or other NIDs, and that the above-listed controllers of databases will convey these data to us. Even this separate (partial) consent can be withdrawn at any time (with future effects), and if you will not wish for REMUS to collect your personal data in the ReMuS registry any more, you can withdraw your consent at any time.

More specific information about particular data transferred and databases used can be obtained via the below-listed contact details. Furthermore, REMUS will continuously inform about its collaboration with the controllers of these databases on its website.

4. Recipients of Personal Data

Operation of the ReMuS registry

Your personal data will be processed in the ReMuS registry by REMUS, Endowment Fund, both manually and automatically, by workers of the fund itself as well as with the help of your MS treatment center and data processors. If your MS treatment center and data processors are involved, your personal data will be processed based on a personal data processing agreement between REMUS, Endowment Fund, and the respective health care provider (as an operator of a MS treatment center) or the respective data processor, with respect to the applicable legal provisions, regulations, and other relevant similar measures.

As of the day of this document's engrossment, REMUS collaborates with the following data processors: VALUE OUTCOMES LLC, CIN: 270 79 33, and MSBase Foundation Ltd, residing at Central Clinical School, Level 6, at the Alfred Centre, 99 Commercial Rd, Victoria 3004, Australia. While conveying data to MSBase Foundation Ltd, your personal data are transferred outside of the European Union, specifically to Australia. Appropriate protection of your personal data is in this case secured, apart from other means, through standard contractual clauses which are in accordance with the Implementing Decision 914/2021/EU on standard contractual clauses for the transfer of personal data to third countries pursuant Regulation (EU) 679/2016, or through conveying data in pseudonymized form only, which prevents the recipient from identifying any particular person.

Scientific Studies and International Collaboration

For the purposes of executing scientific studies, data from the ReMuS registry are as standard conveyed in aggregate and anonymized form (i.e. no specific personal data are conveyed) and exclusively on the basis of a specific and justified request of a third party, for example scientific institutions, health insurance company, the Ministry of Health, manufacturers of medical preparations, etc.

In exceptional cases, personal data may be conveyed to third parties, too, but always in pseudonymized form (without any identification and contact data) and consistently in accordance with the purposes of personal data processing in the ReMuS registry. This may for example involve conveying data as part of the Big Multiple Sclerosis Data Network partnership. In these instances, an appropriate personal data protection agreement is always signed with the respective recipient. This also applies to instances in which personal data are to be transferred to third countries and in which standard contractual clauses are used in accordance with the above-mentioned decision of the European Commission.

Making personal data available will be always decided by a committee consisting of representatives of REMUS, Endowment Fund, members of a specialist society (Neuroimmunology and Liquorology Section of the Czech Neurological Society, member of the Czech Medical Association of J.E. Purkyně), representatives of patients' organizations, and public institutions operating in the protection of public health.

More information about particular scientific studies can be obtained via the below-listed contact details.

5. Time of Personal Data Processing

Your personal data will be processed in the ReMuS registry in an encoded form for the period of your lifetime, since the purposes of their processing can only be fulfilled on the basis of long-term evaluation of the data, and only such long-term monitoring can bring the maximum of relevant information on the course of MS or other NIDs, the effectiveness of their treatment, and the needs of the patients. IMPLUS commits to informing you continuously and in an appropriate way (e.g. by e-mail or through your MS treatment center) about your personal data being still processed in the ReMuS registry.

In case that you withdraw your consent to your personal data processing, or after your death, your personal data will be anonymized in the ReMuS registry, i.e. personal data which might potentially enable your identification will be removed from the registry; the remaining data will be further processed and stored in the ReMuS registry; however, it will be no longer possible to connect these data to your person.

6. Security of Personal Data

REMUS, as well as MS treatment centers and data processors, who participate in your personal data processing in the ReMuS registry, protect your personal data in the ReMuS registry against any unauthorized or accidental access, against their altering, destroying, or loss, against unauthorized transmission, or other unauthorized processing or abuse. Unauthorized persons will not be allowed to access your personal data under any circumstances.

REMUS also protects personal data by encoding them in such way that your first name, surname, national ID number and address cannot be listed during any subsequent scientific processing of your personal data in the ReMuS registry.

7. Rights Related to Personal Data Processing

Apart from your right to withdraw your consent granted to us, you also have, if the requirements of the applicable legal regulations are met, the following rights:

- right to access your personal data that we process
- right to rectify inaccurate data and to complete missing personal data
- right to erasure of your personal data that we process
- right to limit the processing of your personal data
- right to portability of your personal data
- right to object (to be exercised if the legal basis of data processing is legitimate interest of REMUS, Endowment Fund)

You have also the right to lodge a complaint with a supervisory authority which is the Personal Data Protection Office, residing at Pplk. Sochora 27, 170 00 Praha 7, www.uoou.cz.

8. Consent with Participation in the ReMuS Registry

The decision on granting your consent to processing your personal data in the ReMuS registry is your free and voluntary decision, which will not influence your health care in any way. No reward is connected to granting your consent, nor will it provide to you any direct benefits. Information acquired based on processing your personal data for the above-described purposes will, nevertheless, undoubtedly contribute to better understanding of MS and other NIDs, which may lead to improvement of the quality of health care regarding all patients with MS or NIDs, including yourself.

You can withdraw your already granted consent with personal data processing at any time via a written statement addressed to REMUS, Endowment Fund, or to your general practitioner, or by means of an oral statement to your attending doctor in your MS treatment center, who will then record your statement in writing.

9. Ethical Aspects

Before you grant your consent with personal data processing in the ReMuS registry, a doctor will be available to you at your MS treatment center to answer any of your questions concerning this registry. Any other questions regarding the ReMuS registry (e.g. concerning the justification of personal data processing in the registry, the scientific aspects of the registry, etc.) can be addressed to prof. Dana Horáková, MD, Ph.D.

Ethical aspects of the ReMuS registry were evaluated by Ethics committee of General University Hospital in Prague on February 16th, 2023.

10. Identity and Contact Details of Data Controller and Data Protection Officer

Personal data controller is us, i.e. ReMuS, Endowment Fund, CIN: 21453128, residing at Praha 2, Karlovo náměstí 317/5, postal code 120 00, registered in the endowment registry of the Municipal Court in Prague, section N, file 2473, legal successor of IMPULS Endowment Fund (CIN: 26169428), founded in April 6th, 2000. You can ask us any questions concerning personal data processing at our residential address, or contact us via e-mail at: remus@multiplesclerosis.cz, or on the telephone: +420 605 169 222.

It is also possible to address your questions concerning personal data protection to our data protection officer via the e-mail address: poverenec@multiplesclerosis.cz.

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