**Insert Site Logo**

### Participant Information and Consent Form

**[Insert site letterhead and / or logo]**

**Version** [xx] **Dated** [xx]

**Centre / Site Name:** [Insert Centre / Site / Hospital / Institution Name]

**Local Ethics / Legal Tracking Number (if applicable)**: [xxxx]

**Full Study Title:** MSBase: An international registry dedicated to evaluating outcomes data in multiple sclerosis (MS) and other neuroimmunological diseases (NIDs)

**Abbreviated Study Title:** MSBase Registry Observational Study

Principal Investigator: [Insert PI Name]

**Associate Co-Principal Investigator(s):** [Insert Associate Investigator(s) Name(s)]

### Introduction

You are being invited to take part in an international research registry of patients with neuroimmunological diseases including multiple sclerosis (MS), neuromyelitis optica (NMO), anti-MOG and myasthenia gravis (MG). Before you decide whether you would like to take part, it is important that you understand why the research is performed and what it will involve.

This Participant Information and Consent Form is **[x]** pages long. It contains detailed information about the MSBase Registry Observational Study. Its purpose is to explain to you as openly and clearly as possible all of the procedures involved in the MSBase Observational Study before you decide whether or not to take part in it.

Please make sure you have all the pages and please take your time to read the information carefully.

You may wish to discuss the MSBase Observational Study with a relative, friend or your health care provider before you make any decisions. Feel free to do this. Ask us if you have any questions about the information contained within this document or if you would like more information.

### Your consent

Once you understand what the Study is about and if you agree to take part in it, you will be asked to sign the Study Consent Form. By signing the Consent Form, you indicate that you understand the information contained within and that you freely give your consent to participate in the MSBase Observational Research Study.

You will be given a copy of your signed Participation Information and Consent Form to keep as a record.

### What is the purpose of the MSBase Registry?

The MSBase Registry is a research registry. Research registries are also known as a research databases. They collect information about lots of people, often who all have the same health condition

The objective of the MSBase Registry is to enrol patients with supported neuroimmunological diseases from centres worldwide and to follow up with them at least annually, for an ongoing indefinite period. The Registry collects observational health and medical information about a number of neuroimmunological diseases (NIDs), including MS, NMO, anti-MOG and MG.

The MSBase Registry has several aims:

* To collect long-term clinical information from a large group of patients with neuroimmunological diseases, including NMO, anti-MOG, MG and MS, or a single episode of symptoms suggestive of MS.
* To enable researchers to prospectively evaluate long term treatment effects and the safety of current and future disease modifying therapies in standard clinical practice.
* To enable researchers to document disease outcomes in different areas of the world.

The data obtained from the Registry is used in studies that aim to improve quality of care by evaluating outcomes in a large global group of people with NIDs including MS, MG, NMO and anti-MOG. The collected data relating to you may be used for medical or scientific research and may be published in scientific journals.

A Global Scientific Leadership Group of leading MS specialists that reports to the MSBase Foundation will closely monitor and approve any analysis of the data to ensure it is only used in ways that align with the MSBase Foundation’s Mission, Vision and Values and the purposes of its Registry’s Observational Study.

### Procedures

If you meet the eligibility criteria and agree to participate in the Study, you will be asked to visit your neurologist at least once a year, as is the usual minimum time for follow up in your routine clinical care and treatment. As part of your routine visits you may receive clinical assessments, medications, and treatments as determined by your neurologist. No experimental intervention is involved.

### Screening and entry visit

During the screening period you will be evaluated to see if you are eligible for the Study. The screening period will normally consist of one visit. Data relating to your neuroimmunological disease and general health will be recorded including:

* your medical and neuroimmunological disease history including previous tests used to diagnose or monitor your disease such as MRI reports, spinal fluid analysis, evoked potential tests and blood tests. You may not have had some of these tests performed. You will not be required to have extra tests; we will only collect the data on the tests that your neurologist has performed or would normally perform for people with your condition.
* the findings of your neurological examination.
* presence of NIDs and other autoimmune diseases in your family history, if applicable.
* any medications and other treatments, past and present, that you have received for any medical condition.

### Annual visit

The annual follow-up visits will be conducted as part of your routine review with your neurologist and do not require any additional time. Standard assessments and record taking may include:

* A neurological examination such as the Expanded Disability Status Scale (EDSS).
* Tests related to your disease such as MRIs, spinal fluid analysis, evoked potentials, or blood tests, if undertaken.
* All medications for your disease including dose start and stop times.
* Health status questions to monitor the safety of medications used for your disease.
* Pregnancy information and outcomes.

### Relapse visits

If you develop a significant relapse (NIDs or MS attack), it is likely that you will be reviewed by your neurologist or that your neurologist will be notified by your local health care provider. During this visit, if possible, relapse related information should be recorded, this includes:

* A neurological examination (EDSS).
* Treatments received, if any.

### Duration of the research study

The MSBase Registry is a longitudinal Study and will continue as long as funding is available to manage the Study.

### Possible benefits

Although there will be no direct benefits to you as a result of your participation in this Study, the information obtained from this Study may ultimately lead to a better understanding of your disease that could lead to improvements in the quality of care of all people with the same neuroimmunological disease.

### Possible risks

As the MSBase Observational Study collects only observational information with no intervention, there is no risk in participating. The Study does not prescribe or recommend any activity or treatment. The Study data are compiled solely from a review of your relevant medical records.

### Alternatives to participation

Alternatives include being followed up by your neurologist in accordance with usual medical practice and the information that is obtained not being transmitted to the MSBase Registry for research purposes.

### Your privacy and disclosure of information

Your information will be collected by your neurologist or another member of your healthcare team when you have a visit at [insert site name] and will be stored locally at [insert site name].

Information is entered and kept in an electronic monitoring and visualisation tool specifically designed for the purpose of monitoring patients with MS and other NIDs. The monitoring tool and its database are only accessible by approved users and are password protected.

With your consent the information collected by your healthcare team can be shared with the MSBase Registry’s secure central database. Here it can be accessed by approved researchers who are aiming to improve patient outcomes in MS and other NIDs by utilising the global pool of data. The Registry’s central database is held in secure Azure Microsoft servers.

Anytime your information is shared with the Registry, it is first codified by using a process called pseudonymisation. In this process the majority of your personal identifying information is removed from your record and is replaced with a unique code before being shared with the MSBase Registry. Only your month and year of birth, and your gender will be transferred to the Registry because this information is often especially useful or necessary for the investigators/researchers to be able to ask the research questions about MS and other NIDs in a meaningful way.

Once your pseudonymised information reaches the Registry it may be used for current and future studies of MS and other NIDs. It is only possible for approved participating researchers / research service providers to receive the pseudonymised information.

Your identity will not be known to the MSBase Foundation, or any of the participating researchers or research service providers. They will only see codified information which does not identify you. Any information obtained in connection with this Study that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law.

By signing this Consent Form and giving us your permission to participate in the Study, your data will be combined with other patients’ information in the Registry and used for data analyses. Results of the analyses may be used for presentations at meetings or in publications. At times, analyses and reports are also provided to pharmaceutical companies to provide them a better understanding of the effectiveness and safety of their therapies over longer periods of time in a real-world observational setting. The MSBase Foundation may receive funding from pharmaceutical companies and other funders to help cover the costs involved in running and maintaining the Registry and in conducting data analyses.

Medical records that identify you, and the consent form signed by you, will never be made accessible to the MSBase Foundation or the Registry. Your identifiable medical records are controlled by [insert site name] and are stored locally at [insert site name]. However, in order to ensure the quality of data collected, these documents may be inspected from time to time through an independent audit as commissioned by the MSBase Scientific Leadership Group, and in accordance with, and supervised by your healthcare team and/or the responsible ethics committee.

The following information is not transmitted to MSBase:

* Your name
* Your address
* Your phone number
* Your email
* The day you were born (month and year of birth are transmitted)
* Any personal information which may identify you (note: gender is transmitted)

In accordance with relevant [Enter JURISDICTION] law, privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you.

Please contact one of the senior Investigators named below, the head of the centre, centre authority or Data Protection Officer (if applicable) if you would like information or to access your information.

[Insert PI name] and/or [Insert CO-PI name]

Phone: [Insert Phone Contacts].

*Whilst every effort has been made to keep your information secure and private, no system of data storage can be guaranteed to be 100% secure.*

### Results

Outcomes of the studies conducted using information from the MSBase Registry may be presented at scientific meetings and published in medical journals and made available on the public access area of the MSBase website *(www.msbase.org).*

### Further information

If you require further information or if you have any problems concerning this project, you can contact the principal investigator(s) or a member of your healthcare team. The researchers responsible for this project are:

[Insert PI name] and/or [Insert CO-PI name]

**Phone:** [Insert Phone Contacts]

### Other issues

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

**Name:** [Insert Name of Contact e.g. Centre Authority Name / Data Protection Officer Name / Complaints Officer Name]

**Position:** [Insert Position Held]

**Phone:** [Insert Phone Number]

### Participation is voluntary

Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Before you make your decision, a member of the research team will be available to answer any questions you have about Study. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with [insert site name].

### Revocation of consent

Your de-identified information will remain on the Registry indefinitely unless you withdraw from the Study by signing a ‘Revocation of Consent’ Form. Should you decide to withdraw from the Study, any data shared with the MSBase Registry prior to the time of your withdrawal will remain intact.

This Form can be found on the last page of your Patient Information and Consent Form Document (page X). If you decide to withdraw from the MSBase Observational Study, you will need to send the Revocation of Consent form by mail to:

**Principal Investigator, Co-Principal Investigator and/or Centre Authority:** [Insert PI Name / CO-PI Name / Centre Authority]

**Centre Name and Address:** [Insert Centre Name and Address]

**Phone Number:** [Insert Phone Number]

**Fax:** [Insert Phone Number]

**Email:** [Insert Phone Number]

If you need assistance with withdrawing please call [X].

Once this has been received, no further data will be sent to the MSBase Registry, however the information already received by the Registry will remain intact.

### Reimbursements for your costs

You will not be paid for your participation in this Study

### CONSENT FORM

**Version** [xx] **Dated** [xx]

**Centre / Site Name:** [Insert Centre / Site / Hospital / Institution Name]

**Local Ethics / Legal Tracking Number (if applicable)**: [xxxx]

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**Abbreviated Study Title:** MSBase Registry Observational Study

Principal Investigator: [Insert PI Name]

**Associate Co-Principal Investigator(s):** [Insert Associate Investigator(s) Name(s)]

I have read, or have had read to me the Participant Information, and I understand the Information contained within this Participant Information and Consent Form.

**Version** [xx] **Dated** [xx]

I freely agree to participate in this Study according to the conditions in the Participant Information and Consent Form.

The centre, the principal investigator and the healthcare team have agreed not to reveal my identity and personal details if information about this Study is published or presented in any public form.

I will be given a copy of the Participant Information and Consent Form to keep.

Participant’s Name (printed): ………………………………………………………………………………………………

Signature: ………………………………………………………… Date: …………………………….

Name of Witness to Participant’s Signature (printed): ………………………………………………….……

Signature: ………………………………………………………… Date: …………………………….

Declaration by Investigator\*: I have given a verbal explanation of the research Study, its procedures and risks, and I believe that the participant has understood that explanation.

Investigator’s Name (printed): …………………………………………………….………………………………………

Signature: ………………………………………………………… Date: …………………………….

\* A senior member of the healthcare/research team must provide the explanation and provision of information concerning the research Study.

*Note:* All parties signing the Consent Form must date their own signature

### REVOCATION OF CONSENT FORM

*\*For use by participants who wish to withdraw from the MSBase Observational Study*

**Centre / Site Name:** [Insert Centre / Site / Hospital / Institution Name]

**Local Ethics / Legal Tracking Number (if applicable)**: [xxxx]

**Full Study Title:** MSBase: An international registry dedicated to evaluating outcomes data in multiple sclerosis (MS) and other neuroimmunological diseases (NIDs)

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Principal Investigator: [Insert PI Name]

**Associate Co-Principal Investigator(s):** [Insert Associate Investigator(s) Name(s)]

I hereby wish to WITHDRAW my consent to participate in the research Study described above and understand that such withdrawal will not jeopardise any of my treatment or my relationship with [Insert Site Name] and [Insert PI Name].

Participant’s Name (printed): ………………………………………………………………………………………………

Signature: ………………………………………………………… Date: …………………………….

### DATA REMOVAL REQUEST FORM

*\*For use by Centres / Principal Investigator(s) requesting removal of patient data from the MSBase Registry*

**Centre / Site Name:** [Insert Centre / Site / Hospital / Institution Name]

**Local Ethics / Legal Tracking Number (if applicable)**: [xxxx]

**Full Study Title:** MSBase: An international registry dedicated to evaluating outcomes data in multiple sclerosis (MS) and other neuroimmunological diseases (NIDs)

**Abbreviated Study Title:** MSBase Registry Observational Study

Principal Investigator: [Insert PI Name]

**Associate Co-Principal Investigator(s):** [Insert Associate Investigator(s) Name(s)]

On behalf of patient [**insert MSBase patient code**] I hereby request that all data on the patient be removed from the MSBase Registry. The patient has been informed that this request will not jeopardise any treatment or their relationship with the **[Insert Site Name]** or the principal investigator(s) **[Insert PI / CO-PI Name(s)]**.

MSBase centre code: ………………………………………………………………………………………………………

Principal Investigator’s name (printed): …………………………………………………………………………