[**Insert Your Institution Logo**]

**Participant Information and Consent Form**

**Version:** **[Insert version number]** **Dated [Insert date]**

**Site:** [Insert your institution name]

**HREC NO**: [Insert HREC NO if applicable]

**Full Project Title:** MSBase: An International Registry Dedicated to Evaluating Outcomes Data in Multiple Sclerosis (MS) and Other Neuroimmunological Diseases (NIDs). Referred to as “MSBase Study” in this article.

Principal Researcher: [Insert principal researcher name(s)]

**Associate Investigators:** [Insert associate investigator name(s)]

This Participant Information and Consent Form is [insert # of pages] pages long. Please make sure you have all the pages.

**1. Your Consent**

You are invited to participate in an international registry of patients with Neuroimmunological diseases (NIDs) including multiple sclerosis (MS) neuromyelitis optica (NMO), anti-MOG and myasthenia gravis (MG) conducted at [insert your institution’s name] by [insert principal researcher’s name(s)]. This Participant Information contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or local health care worker. Feel free to do this.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign a Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Participant Information and Consent Form to keep as a record.

**2. Purpose and Background**

The MSBase observational registry has several aims:

* To collect long-term clinical information from a large group of patients with NIDs or a single episode of symptoms suggestive of MS.
* To enable researchers to prospectively evaluate long term treatment effects of current and future disease modifying therapies in standard clinical practice, including effectiveness and safety
* 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 the quality of care by evaluating outcomes in a large, global group of people with NIDs

All the collected data will be coded and there is no personal or identifying information contained in the registry. The collected medical and health data relating to you will be used for medical and/or scientific research, including publications in scientific journals. Coded data (data from which you can not be identified) will be transmitted to the registry and may be passed on to other investigators for statistical analyses.

Participation in the registry does not require you to take part in any extra activities. The information collected about your NIDs will be recorded from your routine clinic visits and will be an observation of what occurs in your health patterns. Your treatment and management of NIDs will continue to be at the discretion of your doctor.

The objective of the registry is to enrol as many patients from NIDs treatment centres worldwide and to follow them up at least annually, for an indefinite period. To participate you must have a confirmed diagnosis of NIDs, or a Clinically Isolated Syndrome (CIS)/single episode of symptoms suggestive of MS that could, in the future, evolve into MS.

The sponsor of the MSBase registry and its sub studies is the MSBase Foundation Ltd, a not-for profit organisation. The MSBase Foundation may provide funding to participating research centres, including [insert your institution name], to help offset the costs of data collection.

A Global Scientific Leadership Group (SLG) of leading NIDs specialists that reports to the MSBase Foundation will closely monitor and analyse the data collected through the database.

# 3. Procedures

If you qualify and agree to participate in this MSBase registry, you will be asked to visit your Neurologist at least once a year, as is the usual minimum time for follow up in your treatment. During these routine visits, you will receive clinical assessments, medications, and treatments as determined by your doctor. No experimental intervention is involved.

# *Screening / entry visit*

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

* Your complete medical and NIDs history including all previous tests used to diagnose or monitor your NIDs, 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 NIDs specialist and do not require any additional time. Standard assessments will include:

* A neurological examination relevant to your NIDs, such as the Expanded Disability Status Scale (EDSS) or the Myasthenia Gravis Composite (MGC)
* Tests related to your NIDs such as MRI, spinal fluid analysis, optical coherence tomography (OCT), evoked potentials, electromyography, or blood tests if undertaken would be recorded.
* All medications for your NIDs (dose, start and stop times)
* Health status questions to monitor the safety of medications used for NIDs
* Pregnancy Information and outcomes. This includes questions about the health of any babies up to 12 months of age.

# *Relapse visits*

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

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

# *Duration of research project*

* The registry is a longitudinal project and will continue as long as funding is available to manage the project

**4. Possible Benefits**

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

**5. Possible Risks**

There is no risk in participating in the MSBase Study because it is an observational study which does not prescribe or recommend any activity or treatment. The study data are compiled solely from a review of your medical records. Some people may find questions regarding pregnancy outcomes or infant outcomes distressing. If you experience difficult feelings or distress due to your participation in the research, the research team will be able to refer you to an appropriate counselling service or other appropriate support. [delete if not applicable: This will be free of charge within the public health system].

**6. Alternatives to Participation**

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

**7. Privacy, Confidentiality and Disclosure of Information**

Patient information is initially collected and stored in an electronic patient clinical record kept locally on your [insert the name of your local medical record keeping system]. Your NIDs disease information is entered into an electronic software owned by the MSBase Foundation. This data entry tool is only accessible by the Principal Investigators and members of your institution’s NIDs team and is password protected. Information about your NIDs health is extracted from this tool and sent to the MSBase Registry’s or other relevant NIDs registries’ (e.g., MGBase Registry’s) secure storage location (hosted by Microsoft). Coded MRI scan images or OCT scan images and / or information can also be sent to researchers and research service providers for analysis. Your personal, identifying information will be assigned a unique code so as not to permit any identification before it is sent by your Neurologist to the central registry. Once your coded information reaches the relevant registry it may be used for current and future studies of NIDs by participating NIDs researchers. Whilst every effort has been made to keep your re-identifiable data secure, no system of data storage is 100% secure. Your re-identifiable data will remain indefinitely on the registry unless you sign a revocation of consent form. This form is the last page on your consent document (page [insert # pages]). If you decide to withdraw from the study you will need to send the form by mail to;

[Insert principal researcher name(s)],

[Insert your institution address]

Or Fax to [insert your departmental fax number] or email [[insert your departmental email address]](mailto:msniadmin@alfred.org.au). If you need assistance with withdrawing please call [insert your departmental telephone number].

Once this has been received no further data will be sent to the registries.

Researchers participating will only see coded information which does not identify you. Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. If you give us permission to use your coded information by signing the Consent Form, we plan to include it in the large international database (Registry) and use results related to the large groups of people in this Registry, for presentations at meetings or in publications. At times analyses and reports are also provided to pharmaceutical companies so that they can better understand the effectiveness of their therapies. MSBase Foundation receives funds to cover the cost of conducting these analyses

Medical records that identify you, and the consent form signed by you, will never be made accessible to the international registries. However, in order to ensure the quality of data collected, these documents may be inspected through an independent audit as commissioned by the Scientific Leadership Groups appointed by the MSBase Foundation. This will be done in accordance with and supervised by your treating specialists and/or the responsible ethics committee.

The following information is **not** transmitted to the registries:

* Your name
* Your day of birth (month and year of birth is transmitted)
* Your address
* Your email address
* Your telephone number(s)
* Any personal information which may identify you

Your health and medical information will be stored on the local hospital database and / or on the registries servers for an indefinite period of time.

In accordance with relevant [insert your local jurisdiction district name, e.g. Australia / Victoria] privacy and other relevant laws you have the right to access the information collected and stored by the researchers about you. Please contact [insert the contact person’s name in your institution for the matter, e.g. the principal researcher] ph [insert phone number] if you would like to access your information.

**8. Results**

Outcomes of the studies conducted using information from the registries 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](http://www.msbase.org)) or the MGBase website (www.mgbase.org).

**9. Further Information or Any Problems**

If you require further information or if you have any problems concerning this project, you can contact the principal researcher or the [insert department]. The researchers responsible for this project are [insert principal researcher’s names]

(ph: [insert phone number])

**10. 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 the name of your local contact for this project]

Position: [insert local contact’s position].

Telephone: [insert phone number]

You will need to tell the Complaints Officer the name of the researchers given in section 9 above and please quote the following project ID number [insert ID number if applicable].

**11. 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.

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 your institution name].

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. 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.

However, should you at a later time withdraw from the study, all re-identifiable data entered into the MSBase Study collected until the time of your withdrawal will remain intact.

**12. Ethical Guidelines**

This project will be carried out according to the *[insert the title of your local guideline],* produced by the [insert the name of the institution who produced your local guideline]. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the [insert the name of your local ethic committee].

**13. Reimbursements for your costs**

You will not be paid for your participation in this research project.

CONSENT FORM

Version: [insert version number] Dated [insert date]

Site: [insert your institution name]

**HREC NO:** [insert HREC No, if applicable]

**Principal Investigators:** [insert PI’s name (s)]

Full Project Title: MSBase: An International Registry Dedicated to Evaluating Outcomes Data in Multiple Sclerosis (MS) and Other Neuroimmunology Diseases (NIDs). Referred to as “MSBase Study” in this article.

I have read, or have had read to me and I understand the Participant Information ***version [insert version number] dated [insert date].***

I freely agree to participate in this project according to the conditions in the Participant Information.

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

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

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

Signature Date

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

Signature Date

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

Researcher’s Name (printed) ……………………………………………………

Signature Date

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

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

### REVOCATION OF CONSENT FORM

*(To be used for participants who wish to withdraw from the project.)*

Full Project Title: MSBase: An International Registry Dedicated to Evaluating Outcomes Data in Multiple Sclerosis (MS) and Other Neuroimmunological Conditions (NIDs). Referred to as “MSBase Study” in this article.

**HREC No: 528/12**

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with [insert institution name].

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

Signature Date