

Policy:	Access to the Global MSBase dataset
Category:	SLG
Version No:	4.2
Approved:	28 January 2026
Summary:	<p>The MSBase global dataset is available for access for analysis by Principal Investigators, the Scientific Leadership Group and MSBase senior management. MSBase PIs must meet certain criteria to be considered eligible to request data. All requests for access are reviewed and approved by the Research Committee, a sub-committee of the MSBase SLG. The MSBase Operations team manage the approval process of access requests and log these according to internal procedure.</p>

## 1. Purpose and Scope

The MSBase registry is a collaboration that encourages research in multiple sclerosis and other neuro-immunological diseases. The philosophy underpinning access to the MSBase global dataset reflect the collaborative nature of the registry research projects.

This document provides rules for determining how Principal Investigators and MSBase Foundation staff and contractors can access and use data from the global datasets.

The guidelines do NOT apply to access to data from sub-studies as that is controlled by the sub-study leader. Principal Investigators who opt-in to sub-studies automatically give permission for their data to be included in the study and accessed by the study leader.

## 2. Abbreviations

COO	Chief Operating Officer of the MSBase Foundation
DUA	Data Use Agreement
MD	Managing Director of the MSBase Foundation
MS	Multiple Sclerosis
PI	Principal Investigator
SLG	Scientific Leadership Group
SLG-RC	SLG Research Committee

### 3. Definitions

Board	Means the MSBase Foundation Board of Directors
Centre	Means an MSBase centre and its Principal Investigator and Investigator members
Investigator	Means a person working at a Centre under the lead of the PI who has been authorised to perform tasks in relation to the Centre's participation in the MSBase Registry as delegated by the Centre or its PI
MSBase Statistician	Means the MSBase Foundation Statistician who provides statistical support service to MSBase PIs and the Operations team
Operations team	Means the MSBase Foundation Operations team
Principal Investigator	Means a legally qualified, practicing neurologist at a Centre, who has been given authority from the Centre to transfer pseudonymised data and collaborate in the MSBase/MGBase Registry Observational Study
Research Committee	Means the Research Committee of the MSBase Scientific Leadership Group
SLG or SLGs	Means the Scientific Leadership Group(s) of the MSBase Registry
SLG-RC	Means the Research Committee of the MSBase Scientific Leadership Group
Sub-study	Means studies created on the MSBase web platform by a Principal Investigator (study leader) and where members have opted in
Board	Means the MSBase Foundation Board of Directors

### 4. Responsibility

Primary responsibility rests with the SLG.

### 5. Versions

Version	Amended by	Updates
v4.2 December 2025	Cynthia Tang	<ul style="list-style-type: none"> <li>Added use of AI system in 6.2.b</li> </ul> <p>Eligible persons wishing to access the global dataset.</p>

		<ul style="list-style-type: none"><li>• Added including the reason for the extension and evidence demonstrating substantial progress in 6.2.c Eligible persons wishing to access an updated global dataset.</li><li>• “7. Procedure” updated to reflect the changes above.</li></ul>
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## 6. Policy

All access to the MSBase Registry global dataset will follow these guidelines as developed and approved by the SLG. The guidelines seek to protect PI ownership of centre data and facilitate collaborative research.

### 6.1 Eligibility for access to the global dataset:

Persons in the following roles have the ability to access or request access to the global dataset:

a. **MSBase Principal Investigators**

Leading a specified research project and their nominated team or collaborators, who meeting the following criteria:

- i. contributed a minimum of 50 complete datasets to the MSBase registry (according to the minimum dataset table set out in Appendix 1)
- ii. have uploaded data in the last two years

If the above criteria are not met, the PI may be granted an exemption by the Research Committee if they have established a clear intention of contribution.

b. **SLG delegates**

responsible for SLG led specified research projects and their nominated team or collaborators for a specified project.

c. **MD or delegate**

responsible for contract analyses and reports for pharmaceutical companies prepared as specified research projects.

d. **MD, COO, or MSBase Statistician**

- Responsible for conducting administrative queries (e.g. internal data quality checks, duplicate checks, check of authorship criteria for previous publications) as required for operations, and
- scoping of potential projects proposed by investigators and the pharmaceutical industry (internally managed feasibility questions only), and
- to prepare extract files for SLG approved projects.

## 6.2 Permission to access the global dataset

### a. The MD, COO, or MSBase Statistician for admin use

- not required to obtain permission to access the global dataset for functions as listed in point 6.1d above;
- required to notify administration of all access to data for these purposes, for entry into the Operations team admin data access log;
- the admin data access log will be provided to the Board and SLG on an annual basis, in conjunction with the ECTRIMS meeting for noting.

### b. Eligible persons (listed in 6.1 a to c) wishing to access the global dataset

- Must submit a research proposal for approval to the SLG-RC.
- SLG-RC will assess the proposal with consideration of feasibility, conflict with similar research currently being undertaken by members, adherence to all relevant MSBase policies and procedures (e.g. Authorship).
- Projects approved by the SLG-RC will be forwarded to PIs who will have a two-week timeframe to review the project proposal and choose to opt-out of their centre data being included in the analysis. Opt-outs are recorded in a permission report.
- Following the opt out period, the data requester and SLG chair are required to sign a Data Use Agreement (DUA) that specifies the terms of access to the granted extract of the Global Dataset for a period of 24 months. Once this is executed, the MSBase statistician liaises with the data requestor to grant data access.
- Use of AI systems: MSBase data, whether in whole or in part, must never be uploaded to any public large language model or other AI tool, including public/open AI tools such as ChatGPT, Claude, Gemini and Siri and others. If an investigator wishes to use AI models for any data-related purposes, the only permissible option is a private AI system. Private AI systems are defined as artificial intelligence deployment within a controlled, secure environment (on-premise or private cloud) that keeps sensitive data under an organization's full control. Eligible data applicants must disclose and describe any private AI systems intended for use in the project within the "Methods" section of the data request form. Only private AI systems that have been reviewed and formally approved by SLG-RC may be used in the conduct of the project.

### c. Eligible persons wishing to access an updated global dataset for a proposal previously approved by the SLG-RC

The data requester can request an extension to access the data for an additional 24 months by submitting a request to the SLG-RC, including the reason for the extension and evidence demonstrating substantial progress.

- Where the request is for a limited data extract to update data using only centres included in the original data extract (usually to obtain increased length of follow-up), the request will be considered by the SLG-RC chair. If the chair is satisfied, approval for an updated data extract will be granted. The data recipient receives approval to use the data for 24 months from the date of extract with all other conditions according to the original signed DUA. As the request does not involve new centres, it is not necessary to contact the original centre PIs for opt-out.

- Where the request is to obtain a data extract for a previously approved proposal that would potentially include new centres and may or may not include a minor revision to the project design and study collaborators who have access to raw data, the request will be treated as an extension to the approved proposal that can be considered by the SLG-RC chair. If the chair is satisfied, approval for an updated data extract will be granted and a new DUA must be executed. The data recipient receives approval to use the data 24 months from the date the agreement is executed. **Under this scenario, there is a requirement to contact new PIs to give them an opportunity to opt-out of data contribution before the updated extract is provided.**

In both cases, a request for an updated data extract for any project that has been in progress for four years or more (two-year initial data access term + two-year extension) will be treated as a brand-new project requiring submission of a new data request. This is determined by the date the initial DUA was executed. In this instance, the SLG-RC Chair will complete a duplication and quality check of the new data request before the request is sent to the RC for review and approval.

A new global extract will be granted on one occasion only per project, regardless of whether this is requested during the first or second year of the project.

d. **Eligible persons requesting an updated dataset for a previously approved project with the intention to extend the project to address aims and hypotheses that differ significantly from the originally approved project**

The request should be treated as a brand-new project proposal

### 6.3 Sub-study data access

These guidelines do NOT apply to access to data from sub-studies as that is controlled by the Group Leader. MSBase staff or contractors do not have permission to access sub-study data unless requested in writing by the Group Leader for a specified purpose.

### 6.4 Incident reporting

This policy has been developed to respect the rights of PIs to retain ownership and control of their own data while facilitating the contribution of their centre data to global analyses. In the event that the policy is not followed the MD will report each incident to the Chair of the SLG. If deemed serious, he/she will also report the incident to the SLG and Board. In any case, all incidents will be included in the Incident Register to be noted by the SLG and Board six monthly. Incidents would include but are not limited to, access to data without correct permission, or use of data contrary to the signed DUA such as identification of correct authorship list and access to data beyond the approved collaborator list.

## 7. **Procedure** (*this section is developed by management and is for committee noting only*)

### 7.1 Global dataset extract from the website:

The Operations team is responsible for ensuring that the MSBase Statistician receives a full global data extract of the MSBase registry every month, or at other specified times as instructed by the MD. The extract is performed on the first working day of each month.

### 7.2 Request to access global dataset:

Persons eligible to request access to the global dataset must complete “*MSBase Form: Request to access the global dataset and statistical support*”, ensuring that the proposal complies with the “*MSBase Authorship & Publication Policy*”. The form should be submitted to the MSBase generic email account [info@msbase.org](mailto:info@msbase.org).

Procedure for data requests:

#### 1. Initial approval stage

- MSBase Operations (MO) team ensures the requesting centre has shared a minimum of 50 complete datasets to the MSBase Registry, AND have uploaded data in the last 2 years from the date the request is received. Evidence of meeting these criteria should be saved in the project folder.
- MO ensures the data request form is complete, assigns it a project code and enters it in the ‘Data requests, approvals & output log’.
- MO sends the request to the MSBase COO with cc to the MD. The COO ensures the request is scientifically sound and technically feasible to run; i.e. the data exists in the global registry.
- Once approved, the request is sent to a rotating Research Committee member, who is responsible for completing a duplication and quality check. The member receives a copy of the ‘Data requests, approvals & output log’ to assist in this process, to ensure a similar analysis hasn’t already been completed.
  - If the proposal is a duplication or highly similar to previously completed or current research proposals, the SLG-RC chair is informed. The role of the MSBase SLG is to foster collaboration where competing interest arise wherever possible. Therefore, the SLG-RC chair, assisted by the MD, will attempt to create linkages with PIs who wish to undertake similar research. Decisions will be noted in the “Data requests, approvals & output log”. Complex decisions are discussed amongst the SLG-RC.

#### 2. Research Committee approval

- Proposals cleared by feasibility and duplication checks are then sent to all members of the SLG-RC for comment/approval within one week (ensure to omit any member who many have a conflict of interest, i.e. if they are the data requestor, or involved in the project in any way).
- If the proposal is not approved in its submitted form, the MD or SLG-RC Chair will connect the requesting PI with a mentoring member of the SLG-RC to improve the proposal and re-submit if considered appropriate.

#### 3. Data request sent to MSBase PIs for opt out period

- Approved project proposal is sent to all MSBase PIs (BCC) using the [info@msbase.org](mailto:info@msbase.org) email. PIs are informed of their opportunity to opt out within 2 weeks if they do not want their centre data included in the analyses.
- MO creates an 'MSBase Permission Report' for the project which includes a copy of the email to PIs.
- MO saves any optout emails received from PIs and logs them in the Permission Report.

4. Data Use Agreement is created for signing

- When the two-week opt out deadline is reached, a DUA is created for the project. MO distributes the agreement to the SLG-RC Chair and the data requestor for their signatures, along with a copy of the MSBase Permission Report and any other supporting document via DocuSign.

5. Data Use Agreement is executed and MSBase Statistician is notified for data access

- MO contacts the MSBase Statistician when a project has been internally approved and is ready for data access and liaising with the data requestor. MO forwards to the Statistician the signed DUA (which contains the approved research proposal) and the MSBase Permission Report, which details any opt outs. Where statistical support has also been approved, this should be additionally highlighted to the Statistician.
- The MSBase Statistician, using the most recent monthly global extract, filters centres that have opted out, selects the specific variables required for the study and can perform basic data cleaning in consultation with the data requestor as required.
- The MSBase Statistician liaises with the data requestor and sends the files required for analysis.
- Where the SLG-RC has approved the project for MSBase statistical support, the statistical analysis will be conducted by the MSBase Statistician and is expected to comply with the DUA signed by the data requestor. Note, the data requestor may also have access to the data file if they wish.
- Where raw MRI scans are required for the study, MSBIR must be copied on the correspondence via [msbir.research@sydney.edu.au](mailto:msbir.research@sydney.edu.au)
- Where quantitative MRI data are required, the latest version of iQMS data dictionary must be attached to the same email for the study team's reference.

### 7.3 Request for a time extension to use data for approved proposals:

If the data recipient requires an extension of time to work on the approved data using the original data extract, the following process applies

- the investigator should contact [info@msbase.org](mailto:info@msbase.org) with a brief report (short paragraph) on the status of the project and the reason for the extension request, including the reason for the extension and evidence demonstrating substantial progress
- MO ensures the request is distributed to SLG-RC chair and if no concerns are raised within one week, the extension will be approved for a further two-year, with all other conditions of the DUA still applicable.
- Report and decision to be noted in the "Data requests, approvals & output log".

### 7.4 Request for an updated data extract for an approved proposal:

- a. Where the request is for a limited data extract to update data using only centres included in the original data extract:

- The investigator should contact [info@msbase.org](mailto:info@msbase.org) with a brief report (short paragraph) on the status of the project and the reason for the request for updated data extract.
- This request will be considered by the SLG-RC chair, and if the chair is satisfied, approval for an updated data extract will be granted.
- MO is responsible for advising the MSBase Statistician that the project has been approved for a limited updated extract and forwards to the Statistician the Approved research proposal as detailed on the Data Request Form and the DUA reminding the statistician of any exclusions (centre opt outs).
- The MSBase statistician, using the most recent global extract, filters centres that have opted out, selects the specific variables required for the study and performs some basic data cleaning with liaison with data requester as required.
- Where raw MRI scans are required for the study, MSBIR must be copied on the correspondence via [msbir.research@sydney.edu.au](mailto:msbir.research@sydney.edu.au)
- Where quantitative MRI data are required, the latest version of iQMS data dictionary must be attached to the same email for the study team's reference

b. Where the request is to obtain a data extract for a previously approved proposal that also includes new centres, and could include a minor revision to the project design:

- The investigator should contact [info@msbase.org](mailto:info@msbase.org) with a brief report (short paragraph) on the status of the project and the reason for the request for updated data extract.
- This request will be considered by the SLG-RC Chair, and if the Chair is satisfied, approval for an updated data extract will be granted.
- Under this scenario, **PIs must be emailed with the opportunity to opt-out**.
- Where raw MRI data are required, new MSBIR centre PIs must be emailed with the opportunity to opt-in.
- Once the opt out time has elapsed the MO is responsible for advising the MSBase Statistician that the project has been approved for an updated extract and forwards to the Statistician the Approved research proposal as detailed on the Data Request Form and the DUA reminding the statistician of any exclusions (centre opt outs).
- The MSBase statistician, using the most recent global extract, filters centres that have opted out, selects the specific variables required for the study and performs some basic data cleaning with liaison with data requester as required.
- Where raw MRI scans are required for the study, MSBIR must be copied on the correspondence via [msbir.research@sydney.edu.au](mailto:msbir.research@sydney.edu.au)
- Where quantitative MRI data are required, the latest version of iQMS data dictionary must be attached to the same email for the study team's reference

## 7.5 Request for using an original dataset for a study which contains major difference from the originally approved data request

- The request should be treated as a new project proposal.
- All PIs should be emailed with the opportunity to opt out (using a different template which informs PIs the utilisation of the original dataset).
- Once the opt out time has elapsed, the MO is responsible for preparing an updated permission report and DUA.
- The requester to be informed of the newly opt out centres (including new permanently opt-out centres) and sign the new DUA.

## 7.6 Incident reporting

- In the event that the policy is not followed, the MD should be informed.
- The MD will follow incident reporting guidelines as stated in Section 4.4.

## 8. Related Documentation

MSBase and MGBase Registry Participation Agreement

MSBase SLG regulations

**Policy and Procedure:** MSBase Authorship and Publications

**Form:** Research/analysis proposal and data request

**Form:** Confidentiality / Data Use Agreement

This document updates the *Access to the Global MSBase Dataset Version 4.1* approved by  
SLG April 2025

## Appendix 1: The MSBase Minimum Dataset and Data Required for “Complete Records”

**The MSBase Minimum Dataset and data required for “Complete Records”**

The table below indicates the minimum dataset recommended for clinicians participating in the MSBase Registry. Records are considered complete when the fields circled in red in the table below have been filled.

Fields that are **not** in red text, are all fields that are *recommended* to complete annually, for the purposes of capturing quality data.

**Complete Records fields**

	Field	Frequency	Definition
Patient Profile	Patient ID	Entry Visit	Patient globally unique ID (system creates)
	Sex	Entry Visit	M / F
	Birth date	Entry Visit	Month and year only
	Date of onset	Entry Visit	Date
Visits	Visit Date	Entry & Annual #	Date
	KFS – 8 items	Entry & Annual #	0 to 5 / 0 to 6 / 0 to 12
	EDSS*	Entry & Annual #	0 to 10
Paraclinical tests	Test date	Entry & Annual #	Date
	Test type	Entry & Annual #	MRI, CSF, EP, Biochemistry
Relapses	Relapse Date	Entry & Annual #	Date
	CNS region	Entry & Annual #	Pyramidal, Cerebellum, Brainstem, Sensory functions, Bowel bladder, Visual functions, Neuropsychological functions
	Corticosteroids	Entry & Annual #	Yes, No
Treatments	Treatment ID	Entry & Annual #	Treatment names
	Start date	Entry & Annual #	Date
	End date	Entry & Annual #	Date