INTRODUCTION TO THE MSBASE FOUNDATION GOVERNANCE PACKAGE

Document title:	Action:	Pages for completion/signing:
MSBase and MGBase Registry Participation Agreement	• Signature required (Principal Investigator *and* Centre Authority)	Signatures - page 19
Schedule 1A – MSBase/MGBase Data Processing Agreement (''DPA'')	• Text entry required • Signature required (Principal Investigator *or* Centre Authority)	Text fields – page 1, 21, 22, 26 Signature – page 21
Schedule 2 – MSBase/MGBase Registry Observational Study Protocol	None (review only)	N/A
Schedule 3 – Roles and responsibilities of the MSBase/MGBase Principal Investigator	None (review only)	N/A

1 OBJECTIVE AND BACKGROUND

The MSBase Foundation is dedicated to providing investigators, at no cost, with the best possible logistic solutions to meet the challenges associated with multi-centre investigator-initiated clinical research of neuro-immunological diseases, including multiple sclerosis (MS), neuromyelitis optica (NMO) and myasthenia gravis (MG).

The MSBase Foundation is a Not-For-Profit Company incorporated in Victoria, Australia. It is registered with the Australian Charities and Not-for-profits Commission (ACNC) and holds deductible gift recipient (DGR) status.

This document aims to introduce the MSBase Foundation governance package, which includes the following documents:

- MSBase and MGBase Registry Participation Agreement
    - Schedule 1 – Data Processing Governance Package, including a Data Processing Agreement (Schedule 1A) and Joint Controller Agreement (Schedule 1B)
    - Schedule 2 – MSBase/MGBase Registry Observational Study Protocol
    - Schedule 3 – Roles and Responsibilities of the MSBase/MGBase Principal Investigator

2 AGREEMENT AND GOVERNANCE

The MSBase Foundation provides and administers the web-based MSBase and MGBase Registries (www.msbase.org; www.mgbase.org) and locally installed compatible data-entry software tools – the MSBase Data-entry Software (MDS) and iMed.

The MSBase Foundation runs the MSBase/MGBase Observational Study and aims to provide operational and administrative support to enable Investigators to conduct research analyses and studies by using the MSBase and MGBase Registries and their compatible data-entry systems.

2.1 MSBase and MGBase Registry Participation Agreement – requires signatures

The registry participation agreement (the "**Agreement**") is targeted at centres and their healthcare teams who treat patients with multiple sclerosis and other neuro-immunological diseases and is required for participation in the MSBase and/or MGBase registry observational study and other relevant studies.

The Agreement sets out the governance structure of the MSBase/MGBase Registry, as well as the governance and conditions of the studies made available and provided by the MSBase Foundation.

2.2 Schedule 1 – MSBase/MGBase Data Processing Governance Package

Processing of personal data is necessary for the provision of the services of the MSBase Foundation. Depending on the allocation of responsibility for the processing of personal data between the Centres and the MSBase Foundation, different governing documents apply.

Schedule 1A – MSBase/MGBase Data Processing Agreement (''DPA'') – requires signatures

Schedule 1A, sets forth the centre's rights and obligations as a *data controller* and the MSBase Foundation's rights and obligations as a *data processor*. The MSBase Foundation will only process pseudonymised personal data of patients participating in the MSBase and/or MGBase observational study, on behalf of the centre, and in accordance with the instructions documented in the DPA.

Schedule 1B – MSBase/MGBase Joint Controller Agreement (available upon request, does not form part of the regular governance package)

As regards participation in special sub-studies where personal data is transferred to third parties, the MSBase Foundation is a *joint controller* together with the involved parties. Consequently, the abovementioned Data Processing Agreement will not apply to such processing activities. The joint controllers shall, in such circumstances, enter into a separate Joint Controller Agreement, Schedule 1B, determining their respective responsibilities and roles for compliance with the data privacy obligations in a transparent matter.

2.3 Schedule 2 – MSBase/MGBase Registry Observational Study Protocol

The MSBase/MGBase registry observational study is a longitudinal, real-world study of multiple sclerosis and other neuro-immunological diseases, which invites participation from practicing neurologists and their teams, worldwide. It is jointly owned by all registry observational study investigators of the respective centres.

The study aims to advance investigator-initiated, collaborative epidemiological and outcomes research by utilising uniform minimum datasets to systematically collect and analyse pseudonymised data from consented patients with multiple sclerosis and other neuro-immunological diseases. Detailed information on the study can be found in Schedule 2 of the Agreement.

2.4 Schedule 3 – Roles and responsibilities of the MSBase/MGBase Principal Investigator

The roles and responsibilities of Principal Investigators participating in the MSBase/MGBase registry observational study are explicitly set out in Schedule 3 to the Agreement. It should

be referred to by Principal Investigators on a regular basis and shared with members of their healthcare teams who are involved in any way in the MSBase/MGBase registry observational study.