INTRODUCTION TO THE MSBASE GOVERNANCE PACKAGE

- **MSBase Registry Participation Agreement**
  - Schedule 1 - **Data Processing Agreement**
  - Schedule 2 – **MSBase Registry Observational Study Protocol**
  - Schedule 3 - **Roles and responsibilities of the MSBase PI**

1 OBJECTIVE AND BACKGROUND

The MSBase Foundation ("**MSBase**") is dedicated to providing investigators with the best possible logistic solutions, at no cost, to meet the challenges associated with multi-centre, investigator-initiated clinical research for neuroimmunological diseases, including multiple sclerosis, neuromyelitis optica and myasthenia gravis for example.

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 governance package, which includes the following documents:

- MSBase Registry Participation Agreement
  - Schedule 1 – Data Processing Agreement (with sub-schedules)
  - Schedule 2 – MSBase Registry Observational Study Protocol
  - Schedule 3 – Roles and Responsibilities of the MSBase Principal Investigator

2 AGREEMENT AND GOVERNANCE

MSBase provides and administers the web-based MSBase Registry (www.msbase.org) and locally installed compatible data-entry software tools – the MSBase Data-entry Software and Visualisation Tool (MDS) and the iMed Data-entry Software and Visualisation Tool (iMed).

MSBase runs the MSBase Registry Observational Study and aims to provide operational and administrative support to enable investigators to conduct research analyses and longer-term research studies by using the MSBase Registry and its compatible data-entry systems.

2.1 MSBase Registry Participation Agreement

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

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

2.2 Schedule 1 – MSBase Data Processing Agreement

The MSBase data processing agreement ("**DPA**") sets forth the centre's rights and obligations as a *data controller* and MSBase's rights and obligations as a *data processor*. MSBase will only process the pseudonymised personal data of patients participating in the MSBase observational study, on behalf of the centre, and in accordance with the instructions documented in the DPA.

As regards participation in commercial analyses, as well as special sub-studies where personal data is transferred to third parties, MSBase is a *joint controller* together with the involved parties. Consequently, the abovementioned Schedule 1 (DPA) will continue to apply to certain ongoing processing activities (such as hosting of the pseudonymised data) but does not apply to the additional processing activities required to run the special sub-studies. As such the joint controllers shall, in such circumstances, enter into an additional agreement known as a data sharing agreement or data transfer agreement, to determine their respective responsibilities and roles for compliance with the data privacy obligations in a transparent matter.

2.3 Schedule 2 – MSBase Registry Observational Study Protocol

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

The study aims to advance investigator-initiated, collaborative epidemiological and outcomes research by utilising a uniform minimum dataset to systematically collect and analyse pseudonymised data from consented patients with multiple sclerosis and other neuroimmunological 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 Principal Investigator

The roles and responsibilities of principal investigators participating in the MSBase 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 registry observational study.