

*MSBase Foundation Ltd
The Melbourne Brain Centre
The Royal Melbourne Hospital
Grattan Street
Parkville
VICTORIA 3050
Australia*

15.11.2020

Dear HRA & Devolved Nation Research Governance Assessors/Reviewers

Re: MSBase Registry (IRAS:286711) IRAS categorisation and exemption from study-wide governance assessment and C&C processing.

The MSBase Registry is a longitudinal, strictly observational Multiple Sclerosis database open to all practicing Neurologists and their teams, worldwide. In collaboration with participating Neurologists, the MSBase Registry has established a unique, web-based platform dedicated to sharing, tracking and evaluating outcomes data in Multiple Sclerosis (MS) and other Central Nervous System (CNS) demyelinating diseases. In particular, MSBase aims to advance multi-centre, multi-national epidemiological and outcomes research by providing a freely accessible resource to compile, combine, compare and analyse large datasets

As per the application documentation, the MSBase Registry is hosted outside of the UK in Australia. I have been previously advised by the HRA enquiry line (see correspondence enclosed) that, under Section 11 of the Standard Operating Procedures for Research ethics Committees, MSBase cannot therefore undergo a voluntary UK REC review as a research database/registry. As directed, in order to enable review of the arrangements for recruitment of patients via the NHS (rather than the registry management arrangements), the IRAS application has been submitted as a “*Study limited to working with data (specific project only)*”.

However, as MSBase is a research registry, it falls outside of the scope of the UK Policy Framework for Health and Social Care Research and, as such, does not require governance assessment beyond REC review. For the same reason, the project does not require confirmation of C&C or governance permissions at participating sites and so no OID or SoECAT have been provided with this submission. A cover letter to all participating sites (enclosed) will clarify this and explain the inconsistency in IRAS study type which was selected only in order to enable REC review of the recruitment arrangements for NHS/HSC patients as registry participants.

Please do not hesitate to contact me to discuss any aspect of this submission.

Yours sincerely



Dr Orla Gray
Consultant Neurologist/U.K. Chief Investigator